S. HRG. 107–720

MEDICARE PAYMENTS FOR MEDICAL SUPPLIES

HEARING

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED SEVENTH CONGRESS

SECOND SESSION

SPECIAL HEARING

JUNE 12, 2002—WASHINGTON, DC

Printed for the use of the Committee on Appropriations

Available via the World Wide Web: http://www.access.gpo.gov/congress/senate

U.S. GOVERNMENT PRINTING OFFICE

82–251 PDF WASHINGTON : 2002

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2250 Mail: Stop SSOP, Washington, DC 20402–0001

COMMITTEE ON APPROPRIATIONS

ROBERT C. BYRD, West Virginia, *Chairman*

DANIEL K. INOUYE, Hawaii	TED STEVENS, Alaska
ERNEST F. HOLLINGS, South Carolina	THAD COCHRAN, Mississippi
PATRICK J. LEAHY, Vermont	ARLEN SPECTER, Pennsylvania
TOM HARKIN, Iowa	PETE V. DOMENICI, New Mexico
BARBARA A. MIKULSKI, Maryland	CHRISTOPHER S. BOND, Missouri
HARRY REID, Nevada	MITCH MCCONNELL, Kentucky
HERB KOHL, Wisconsin	CONRAD BURNS, Montana
PATTY MURRAY, Washington	RICHARD C. SHELBY, Alabama
BYRON L. DORGAN, North Dakota	JUDD GREGG, New Hampshire
DIANNE FEINSTEIN, California	ROBERT F. BENNETT, Utah
RICHARD J. DURBIN, Illinois	BEN NIGHTHORSE CAMPBELL, Colorado
TIM JOHNSON, South Dakota	LARRY CRAIG, Idaho
MARY L. LANDRIEU, Louisiana	KAY BAILEY HUTCHISON, Texas
JACK REED, Rhode Island	MIKE DEWINE, Ohio

TERRENCE E. SAUVAIN, *Staff Director*
CHARLES KIEFFER, *Deputy Staff Director*
STEVEN J. CORTESE, *Minority Staff Director*
LISA SUTHERLAND, *Minority Deputy Staff Director*

SUBCOMMITTEE ON DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES

TOM HARKIN, Iowa, *Chairman*

ERNEST F. HOLLINGS, South Carolina	ARLEN SPECTER, Pennsylvania
DANIEL K. INOUYE, Hawaii	THAD COCHRAN, Mississippi
HARRY REID, Nevada	JUDD GREGG, New Hampshire
HERB KOHL, Wisconsin	LARRY CRAIG, Idaho
PATTY MURRAY, Washington	KAY BAILEY HUTCHISON, Texas
MARY L. LANDRIEU, Louisiana	TED STEVENS, Alaska
ROBERT C. BYRD, West Virginia	MIKE DEWINE, Ohio

Professional Staff
ELLEN MURRAY
JIM SOURWINE
MARK LAISCH
ADRIENNE HALLETT
ERIK FATEMI
BETTILOU TAYLOR *(Minority)*
MARY DIETRICH *(Minority)*
SUDIP SHRIKANT PARIKH *(Minority)*
CANDICE ROGERS *(Minority)*

Administrative Support
CAROLE GEAGLEY

CONTENTS

MEDICARE PAYMENTS FOR MEDICAL SUPPLIES

WEDNESDAY, JUNE 12, 2002

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:34 a.m., in room SD–124, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Murray, and Specter.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. The Subcommittee on Labor, Health and Human Services, and Education will come to order.

This morning the subcommittee will once again examine the appropriateness of Medicare payments for medical supplies. Over the past 12 years, this subcommittee has taken a leadership role in trying to reduce the losses to the American taxpayer and to millions of Medicare beneficiaries due to waste in the Medicare program.

The good news is we have made some progress. 5 years ago, the Inspector General found that about $23 billion, or about 14 percent of Medicare funds, were lost to mispayments. Through the bipartisan efforts of this subcommittee and others here today, that has been cut in half. In addition, we have reduced waste in payments for oxygen equipment by over $1 billion. And we have demonstrated that real savings can be achieved through competitive bidding.

But it is not even close to time to be taking a victory lap. Today we are releasing the results of a new investigation by the Inspector General of Health and Human Services. At my request, they analyzed Medicare's payments for 16 commonly used medical supply items. The results are indeed staggering. The report makes it clear that American taxpayers and Medicare beneficiaries are still being taken to the cleaners. The IG report found that Medicare is paying up to eight times more than another Federal Government agency, the Veterans Administration. In fact, the IG's analysis shows that Medicare is paying more than double the VA rate for 11 of the 16 items. They found that for just the 16 items they reviewed, if Medicare simply paid the same rate as the Department of Veterans Affairs, taxpayers and Medicare beneficiaries who pay 20 percent of the cost of supplies they use would save nearly $1 billion a year. That is a savings of over half the current $1.7 billion cost.

Now, I know there are some real differences in the Medicare and VA systems, but because Medicare is by far the largest purchaser of these items, it should be able to drive an even better bargain than the VA. Despite this, the Inspector General found that Medicare is paying even more than if you or I walked off the street to the corner drugstore. In fact, we would save over $80 million a year on these items if Medicare just went down to the local drugstore and paid the average retail rate.

It is even more disturbing that Medicare has the authority it needs to immediately put a halt to this fleecing of taxpayers and our seniors. Yet, it has not acted.

In 1997, based on evidence gathered at our hearings, this subcommittee, then under the guidance and direction of Senator Specter, gave Medicare new streamlined authority to reduce Medicare payments that are grossly excessive.

In 1999, HCFA, now CMS, proposed very modest reductions that would save $487 million over 5 years. They were temporarily stopped from proceeding by actions taken in the other body. But that prohibition ended nearly 2 years ago when the GAO issued their report supporting Medicare's proposed actions.

I am very concerned that Medicare has failed to use its authority to protect the taxpayers and our seniors, and I am hopeful to learn today of their plans to move ahead without further delay.

I also intend to continue to push to get Medicare the same authority that the VA has used so effectively: good, old-fashioned, free enterprise, competitive bidding. I am very, very happy and pleased that the Bush administration in their budget request is backing this long overdue reform, and I look forward to working with them to make sure that competitive bidding, with appropriate safeguards, as we all know, for rural areas and highly customized items—I hear that all the time—is made a part of any Medicare package that passes this year. In other words, it is my intention to make sure that if any Medicare thing passes this year, we are going to work with the administration to get competitive bidding in there.

In closing, again I just want to say that this is really important. First, there are few other Government programs so important in the daily lives of so many Americans as Medicare. Secondly, it is especially grating on me as a Senator from Iowa that while Medicare is overpaying for these medical supplies, it is underfunding services in my State. Iowa is on the bottom, number 50, in terms of reimbursements. The money we are wasting on medical supplies could be much better spent bringing greater fairness to States like mine, let alone trying to get a decent prescription drug benefit. That is why we have got to move ahead aggressively on this.

We have a great panel of witnesses today, and I look forward to the important contributions each of them will make to our hearing today.

I thought I might, again for the benefit of some of those who are here, point out some of the items we are talking about. The Inspector General I know will also and so will the Administrator of CMS.

But again, just to set the stage for what we are talking about, first, consider blood glucose test strips. Medicare paid $38.32 for 50. The VA pays $19.50 for 50. So, I had Jim here go down to the

drugstore. He actually went to Costco. I am not here plugging Costco, but anyway he went to Costco. Now, I said that Medicare paid $38.32 for 50. We went to Costco and got 100 for $70; plus, they threw in free lancets, and Medicare also pays for the lancets. So, maybe we can go to Costco and have some savings.

The next thing is saline solution. This is the one that really gets me. Medicare is paying $8.68 a liter. Now, saline solution is saltwater for any of you who do not know what that means. It is sterile saltwater. VA is paying $1.02 a liter. I would like to know what it costs to make it. If it costs over 15 or 20 cents, I would be surprised.

We have a TENS unit. Actually this is mine. I had some muscle problems one time and I got one of these. Medicare is paying $365. This is a TENS unit. It takes a couple of AA batteries, and you put them on if you have a muscle spasm or something like that in your back. Actually it is a pretty good device. It does work. Medicare pays $365. The VA is paying $165 for these.

Here I have a blood glucose monitor that takes those test strips. Actually this is one of the success stories that CMS has done. They were paying $211 for this, and we found you could get it locally for $57 and that is what Medicare pays for it now. They are paying $57 for this. That is just one of the items that was a great success. That alone—just this one item—has saved $25 million in the last 5 years.

PREPARED STATEMENT

Another example is the commode chair that you see all the time in hospitals. A simple commode chair. Medicare is paying $109.74. The VA is paying $32.30 for them.

That just gives you some idea of the discrepancies that were found in the IG's investigation of this. That is just a few of 16 items.

[The statement follows:]

PREPARED STATEMENT OF SENATOR TOM HARKIN

Good Morning. The Subcommittee will come to order. This morning the Subcommittee will once again examine the appropriateness of Medicare payments for medical supplies. Over the last 12 years, this Subcommittee has taken a leadership role in trying to reduce the losses to the American taxpayer and millions of Medicare beneficiaries due to waste in the Medicare program.

The good news is we've made some real progress. Five years ago, the Inspector General found that $23 billion or about 14 percent of Medicare funds were lost to mispayments. Through the bipartisan efforts of this Subcommittee and others here today, that has been cut in half. In addition, we've reduced waste in payments for oxygen equipment by over $1 billion. And we have demonstrated that real savings can be achieved through competitive bidding.

But it is not even close to being time to take a victory lap. Today, I am releasing the results of a new investigation by the Health and Human Services Inspector General. At my request, they analyzed Medicare's payments for 16 commonly used medical supply items. The results are staggering. The report makes it clear that American taxpayers and Medicare beneficiaries are still being taken to the cleaners. I'll make analogy to another example of government waste. Remember a number of years ago we found that the Pentagon was paying $500 for a toilet seat?

Well, the good news is, the Pentagon's no longer paying that price. The bad news is, Medicare is.

The IG report found that Medicare is paying up to 8 times more than another federal government agency, the Veterans Administration. In fact, the IG's analysis shows that Medicare is paying more than double the V.A. rate for 11 of the 16 items

studied. They found that for just the 16 items they reviewed, if Medicare simply paid the same rate as the V.A. taxpayers and Medicare beneficiaries—who pay 20 percent of the cost of supplies they use—would save nearly $1 billion a year. That's a savings of over half the current $1.7 billion cost.

Now there are some real differences in the Medicare and V.A. systems. But because Medicare is by far the largest purchaser of these items, it should be able to drive even an better bargain than the V.A. Despite this, the IG found that Medicare is paying even more than if you or I walked off the street to the corner drug store. In fact, we would save over $80 million a year if Medicare just paid the average retail rate.

It is even more disturbing that Medicare has the authority it needs to immediately put a halt to this fleecing of taxpayers and our seniors, yet is refusing to act. In 1997, based on evidence gathered at our hearings, we gave Medicare new streamlined authority to reduce Medicare payments that are "grossly excessive." In 1999, HCFA (now CMS) proposed very modest reductions that would save $487 million over 5 years. They were temporarily stopped from proceeding by Congress.

But that prohibition ended nearly 2 years ago when the GAO issued their report supporting Medicare's proposed action.

I am very concerned that Medicare has failed to use it's authority to protect the taxpayer and our seniors. I'm hopeful we'll learn today their plans to move ahead without further delay. I also intend to continue my push to give Medicare the same authority the V.A. has used so effectively—good old-fashioned free enterprise competitive bidding. Im pleased to learn that the Bush Administration is now backing this long overdue reform and look forward to working with them to make sure competitive bidding—with appropriate safeguards for rural areas and highly customized items—is made part of any Medicare package this year. That is the real long-term solution.

In closing, I want to say why this is all so important. First, there are few other government programs so important in the daily lives of so many Americans as Medicare. Second, it is especially galling to me as Senator from Iowa that while Medicare is overpaying for these medical supplies, it is woefully under funding services in my state. Our state is dead last by some measures in Medicare payments per beneficiary, receiving less than half that of some other states. The money we are wasting in medical supplies could be much better spent bringing greater fairness to states like mine. Let along the need for a decent prescription drug benefit. That is why we can't fail to act.

We have a great panel of witnesses today and I look forward to the important contributions each of them will make to our hearing today.

Senator HARKIN. So now we will turn to our Government witnesses. First we have the Inspector General of the Department of Health and Human Services.

Senator SPECTER. Well, first, you have your ranking member.

Senator HARKIN. I am sorry.

Why do I not introduce them. Then I will turn to you.

Senator SPECTER. You give up the chairmanship, look what happens.

Senator HARKIN. Both of us have chaired this subcommittee, going back more than 12 years. Senator Specter picked it up during his chairmanship, and now we are back again. It has been truly a bipartisan effort to try to get a handle on this.

Senator SPECTER. I never bypassed you for a commode chair, not in all those years.

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Thank you very much, Mr. Chairman. Just a comment or two.

I commend you, Senator Harkin, for this hearing. As Senator Harkin has commented, he and I have changed the gavel and it has been a seamless exchange, which is the way Congress ought to function. We both subscribe to the basic principle that if you want to get something done in Washington, you have to be willing

to cross party lines, and I think this subcommittee for the last 12 years has been exhibit A.

Today's hearing is a very important hearing using as an example 16 items on the agenda where the total savings would have been $958 million, almost $1 billion for 1 year. But the question on my mind is, what more is there there? Perhaps Ms. Aronovitz from GAO can answer that question for us further, or perhaps Mr. Scully or Ms. Rehnquist.

I welcome Tom Scully and Janet Rehnquist here for this hearing. I believe this is the first time that they have appeared before the committee, since taking over the new job. We are very pleased with your credentials and your obvious competency.

But this is a big, big subject, and right now we are struggling in the conference to add things to Medicare on quite a number of lines. People come forward very frequently and want to add something to Medicare. Customarily they are very good ideas, and at the top of the agenda is the prescription drug issue. Last year when we had a $5.6 trillion surplus, we were talking about $400 billion for Medicare, though that number has since been pared to $190 billion, and we really do not know what it will end up at. We are long past due in providing prescription drugs. But if you pick up $958 million here—as Everett Dirksen said, you pick up a billion here, you pick up a billion there, pretty soon you have got enough money for Medicare prescription drugs.

The business about what the VA is doing is really very, very obvious. We have been through that on the Veterans Affairs Committee, which I chaired for 6½ years. Now Senator Rockefeller has picked it up, again on a bipartisan basis. HHS bought a lot of drugs in response to the terrorist attack, and there is a real question in my mind as to whether that might have been done a lot cheaper through the VA. VA has such enormous purchasing power, that they can get things cheaper.

I regret that I am not going to be able to stay, but I would hope that the witnesses would address the question as to why Medicare does not take advantage of the buying power of your brother organization.

But this is a big hearing. There are big items involved here. We would prefer not to get involved in the publicity on the expensive hammer, the expensive toilet seat, or the rest of it, which has plagued DOD for years, but get right down to what can be done to save this money and apply it elsewhere where it is needed.

Again, Mr. Chairman, I thank you for the introduction.

STATEMENT OF JANET REHNQUIST, INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator HARKIN. Thank you, Senator Specter.

First, I would like to introduce Janet Rehnquist who was sworn in as Inspector General of the U.S. Department of Health and Human Services on August 8, 2001. Prior to joining HHS, Ms. Rehnquist served for several years as an Assistant United States Attorney for the Eastern District of Virginia. Ms. Rehnquist also served in the White House as associate counsel to the President. She also served as counsel to the permanent Subcommittee on Investigation for the United States Senate. Ms. Rehnquist received

her bachelor of arts degree with honors from the University of Virginia and her juris doctorate from the University of Virginia Law School.

It would be my intention to hear from you, Ms. Rehnquist, and then Ms. Aronovitz, and then Mr. Scully. Then we will just open it up for discussion. But welcome to the committee. All of your statements will be made a part of the record in their entirety, and Ms. Rehnquist, please proceed as you so desire.

INSPECTOR GENERAL REPORT ON MEDICAL EQUIPMENT AND SUPPLIES

Ms. REHNQUIST. Thank you, Mr. Chairman. Good morning. I am Janet Rehnquist, Inspector General of the Department of Health and Human Services, and I appreciate this opportunity to appear before you today regarding the important issue of Medicare reimbursement for medical equipment and supplies.

Mr. Chairman, the results of our work have shown consistently that Medicare and its beneficiaries pay too much for medical equipment and supplies. This continuing problem needs a solution to reduce the amount of Medicare overpayment. The taxpayers deserve it, and as you have stated before, the beneficiaries should settle for nothing less.

As you have stated, the problems we are discussing today are not new. The OIG has performed numerous other reviews which consistently found that Medicare pays too much for certain items of medical equipment and supplies because Medicare reimbursement rates are based on charges submitted to the program in 1987. As a result, Medicare payments can bear little resemblance to prices available in the marketplace or to the actual cost of manufacturing and distributing the equipment.

Although Congress and the administration have done much to improve Medicare's reimbursement for medical equipment and supplies, we believe that even more needs to be done. Mechanisms such as inherent reasonableness authority and competitive bidding demonstrations are promising approaches to reduce excessive reimbursement.

Medicare Part B expenditures for all medical equipment and supplies totaled more than $6.8 billion in the year 2000, and I think it is important to note that beneficiaries paid more than $1.3 billion out of their own pockets in that year alone.

CAPPED RENTAL EQUIPMENT

On a related issue, a report we are releasing today, entitled Medicare Maintenance Payments for Capped Rental Equipment, in which we reviewed Medicare maintenance payments made in the capped rental payment category, we found that Medicare could save approximately $100 million per year by eliminating maintenance payments and paying only for equipment repairs when needed. CMS concurred with our recommendation to eliminate maintenance payments and will seek legislation to eliminate the purchase option for equipment in the capped rental category.

COMPARISON OF PRICES PAID BY MEDICARE AND OTHER CONSUMERS

Mr. Chairman, you asked my office to compare the prices Medicare pays for medical equipment and supplies with the prices paid by other health care consumers. At your request, we compared median 2002 Medicare prices for 16 DME and supply items to the median prices of the Department of Veterans Affairs, Medicaid, the Federal Employee Health Benefit Plan, and retail suppliers. This work, in addition to the report we are releasing today, illustrates again that Medicare pays too much for DME and supply items compared to their consumers. In our comparison, we found the Medicare's reimbursement was greater than the VA median price for 15 of the 16 items. Potential savings would be $958 million per year if Medicare were to adopt these prices.

Now, as you know, there are distinctions between Medicare and the VA which some say make this comparison like apples and oranges. However, even with a 67 percent markup to account for the distinction between Medicare as a payor and VA as a larger purchaser, Medicare's potential savings would be approximately $440 million a year.

We also found that Medicare reimbursement was more than Medicaid reimbursement for 15 of the 16 items. If Medicare used the median Medicaid prices for reimbursement on these items, the program could have saved $193 million per year.

Medicare reimbursement was more than the FEHB plan's median price for 15 of the 16 items also. If Medicare were to reimburse based on the FEHB plans, the program could save $118 million.

INHERENT REASONABLENESS AND COMPETETIVE BIDDING

Medicare prices were more then the median retail price for 10 of the 16 items. Potential Medicare savings would reach $84 million if Medicare used median retail prices. In your demonstration, that would be the Costco or the drugstore down the street prices.

There is obviously a huge range of prices and Medicare's overpayment for DME adversely affects the trust fund and the beneficiaries. However, in terms of solutions, we believe the Government has at least two options designed to begin solving the problem of excessive DME reimbursement: the inherent reasonableness authority and the competitive bidding process.

Inherent reasonableness authority is a vital tool for CMS to adjust unreasonably high or low reimbursement rates for medical equipment and supplies. The inherent reasonableness process, created by the Social Security Act and related Medicare regulations, permitted CMS to use other pricing methods to make unreasonable DME payments analogous to current market prices. CMS has attempted to use this tool in reducing Medicare payments. However, congressional concerns resulted in the suspension of the process until a GAO report on the subject was issued and a final rule published.

The GAO report, issued in July 2000, found that CMS' authority was reasonable and justified. The remaining task is to promulgate a final rule so CMS can exercise its authority.

A second tool that shows promise for reducing excessive payments is the competitive bidding demonstration project undertaken by CMS. Competitive bidding is where suppliers are required to submit bids to Medicare if they wish to provide beneficiaries with certain types of DME equipment. As you know, Medicare payments for medical equipment and supplies are based on fee schedules, but studies show that under these fee schedules, suppliers have been able to charge Medicare beneficiaries higher prices than those charged in many retail outlets for some medical equipment and supplies.

CMS has conducted competitive bidding demonstrations with promising results. Through competitive bidding, CMS estimates 17 percent, or $1.3 million, annual savings for Medicare beneficiaries in Polk County, Florida alone. Additionally, Medicare implemented a competitive bidding demonstration in San Antonio, Texas where CMS estimates a 22 percent savings for the 23-month demonstration period. Competitive bidding used in conjunction with other mechanisms like inherent reasonableness adjustments will go a long way to help alleviate Medicare excessive payments.

INVESTIGATIONS

In addition to CMS' tools to reduce excessive payments, the OIG has aggressively investigated individuals and entities that have defrauded our programs in this area. Between 1996 and 2001, our investigations led to 88 successful criminal prosecutions of DME suppliers and 82 civil settlements or judgments. Together, these investigations resulted in more than $277 million in restitutions, fines, and penalties being ordered by the courts. And the OIG imposed 166 exclusions on DME companies, their owners or employees.

Mr. Chairman, I see my time has expired and I would be happy to answer any questions.

Senator HARKIN. No, go right ahead. Finish.

Ms. REHNQUIST. Just a couple more points. I guess in conclusion I would like to just say that all of our work and I know that the work of your staff too leads us to the same conclusion, and that is that Medicare does pay too much for some items of equipment and supplies. We believe that fundamental reform is needed to ensure that Medicare and its beneficiaries pay a fair price. But fortunately, through inherent reasonableness authority and competitive bidding, these valuable tools I think will be very effective in reducing these excessive payments.

PREPARED STATEMENT

The administration and Congress are working together to expand the bidding demonstrations, and as you mentioned, I think this will go a long way towards making sure that Medicare pays a fair and not an excessive price. The taxpayers and the beneficiaries deserve nothing less.

Thank you for the opportunity to discuss these important issues and I will be happy to answer any questions.

[The statement follows:]

PREPARED STATEMENT OF JANET REHNQUIST

Good morning, Mr. Chairman and Members of the Subcommittee. I am Janet Rehnquist, Inspector General of the Department of Health and Human Services. I appreciate this opportunity to appear before you today to discuss some of the issues we have encountered with fraud, waste and abuse related to Medicare reimbursement for medical equipment and supplies.

We continue to find that Medicare and its beneficiaries pay too much for medical equipment and supplies. You have specifically asked us to compare the price Medicare pays for certain medical equipment and supplies with that of other payers, including the Department of Veterans Affairs (VA), Medicaid, Federal Employee Health Benefit (FEHB) plans, and retail suppliers. Our price comparison demonstrates that Medicare overpays for some medical equipment and supplies.

The problems that we are discussing today are not new. We have done numerous reviews over the years documenting excessive reimbursement for medical equipment and supplies. The Centers for Medicare & Medicaid Services (CMS), the General Accounting Office (GAO) and Members of Congress such as yourself, Mr. Chairman, have done much to improve Medicare's reimbursement for medical equipment and supplies. Improvements include creating supplier standards, centralizing claims processing into four regional carriers, and reducing oxygen reimbursement by 30 percent. In addition, inherent reasonableness authority and competitive bidding demonstrations have been promising approaches to reduce excessive reimbursement. We believe that even more has to be done, and my testimony today will outline some specific steps to reduce or eliminate problems that continue today.

BACKGROUND

Medicare Part B expenditures for all medical equipment and supplies totaled more than $6.8 billion in 2000, of which beneficiaries paid more than $1.3 billion out of their own pockets. Medicare covers certain medical equipment and supplies, which include several categories of items. Durable medical equipment (DME) are items that can withstand repeated use and include oxygen equipment, hospital beds, wheelchairs, and other equipment that physicians prescribe for home use. Medicare Part B also covers certain drugs necessary for the effective use of DME, including albuterol for use with a nebulizer. Prosthetic devices replace all or part of a body organ. Medicare covers enteral and parenteral nutrition therapy under this benefit. Medical supplies include catheter, ostomy, incontinence, and wound care supplies. Medicare also covers braces and artificial limbs.

RECENT OIG WORK

We have conducted numerous studies in recent years, all showing that Medicare pays too much for certain medical equipment and supplies.

Maintenance Payments for Capped Rental Equipment.—In a report we are releasing today entitled *Medicare Maintenance Payments for Capped Rental Equipment*, we reviewed Medicare's maintenance payments that are made under the capped rental payment category. We found that Medicare paid substantially more for maintenance on rented equipment than repairs on purchased equipment. Medicare pays for maintenance even if the supplier does not service the equipment. Furthermore, our additional analysis of supplier documentation found only 9 percent of the capped rental equipment actually received any maintenance and servicing. We estimated that Medicare could save approximately $100 million per year by eliminating maintenance payments and, instead, pay only for repairs when needed. CMS concurred with our recommendation to eliminate maintenance payments and will seek legislation to eliminate the purchase option under the capped rental category.

Respiratory Assist Devices.—In June 2001, we issued a report entitled*Respiratory Assist Devices With Back-up Rate*. We concluded that the current Medicare payment method used for bi-level respiratory assist devices with back-up rate is inappropriate. Medicare could save $11.5 million annually if this item were classified as a "capped rental" item rather than an item needing "frequent and substantial service". CMS is currently in the process of making this change.

Prescription Drugs Used with Medical Equipment.—In March 2002, we released a report entitled *Excessive Medicare Reimbursement for Albuterol*. We found that Medicare and its beneficiaries would save $264 million a year if albuterol were reimbursed at the median VA price and between $226 million and $245 million if reimbursed at prices available to suppliers. A separate March 2002 report entitled *Excessive Medicare Reimbursement for Ipratropium Bromide* found that Medicare and its beneficiaries would save $279 million a year if ipratropium bromide were reim-

bursed at the median VA prices and between $223 million and $262 million a year if reimbursed at prices available to suppliers.

Blood Glucose Test Strips.—In a June 2000 report entitled *Blood Glucose Test Strips: Inappropriate Medicare Payments*, OEI–03–98–00230, we found that Medicare allowed $79 million for blood glucose test strip claims with missing or flawed documentation. Orders for 25 percent of the sampled claims failed to establish beneficiaries' eligibility for the supplies. Another 21 percent of claims had incomplete orders. We found that suppliers submit claims for test strips at irregular intervals, making it difficult to identify overlapping claims, claims without correct supporting documentation, and claims for excessive numbers of test strips. We recommended that CMS take several steps to promote compliance with Medicare guidelines for blood glucose test strips.

We have performed numerous other reviews which consistently found that Medicare pays too much for certain items of medical equipment and supplies because Medicare reimbursement rates are based on charges submitted to the program in 1987. As a result, Medicare payments can bear little resemblance to prices available in the marketplace or to the actual cost of manufacturing and distributing the equipment.

PRICE COMPARISONS FOR 16 MEDICAL EQUIPMENT AND SUPPLY ITEMS

The price comparisons that you requested confirm once again that Medicare pays more than other payers for certain medical equipment and supplies. We compared Medicare payment rates for medical equipment and supplies to the rates of other payers, and provided an estimate of potential savings if the Medicare program were to adopt the rates of these payers.

Our analysis shows that health care consumers, Federal health insurance plans, State Medicaid agencies, and the VA pay less than Medicare for some of the medical equipment and supplies we reviewed. However, this analysis was not designed to follow the same process for rate setting purposes that CMS will need to employ using the inherent reasonableness authority authorized in Section 4316 of the Balanced Budget Act of 1997. In order for CMS to affect a payment reduction for items in our analysis, they would have to conduct a separate inherent reasonableness determination in accordance with procedures set forth in regulations. As discussed later in my testimony, revised standards have to be promulgated before this authority can be utilized.

Also, unlike Medicare, which is a payer of services and not a provider of services, the VA generally obtains medical equipment and supplies by direct acquisition from manufacturers and wholesalers. The prices that the VA pays for medical equipment and supplies provide a rough estimate of the wholesale prices available to large purchasers. These prices do not take into account the Medicare supplier costs associated with getting an item to a Medicare beneficiary.

For our analysis, we compared the median Medicare price for 16 medical equipment and supply items with the median prices from the VA, State Medicaid agencies, fee-for-service FEHB plans, and retail suppliers. Twelve of these items were researched by the Chairman's staff in 1996. The remaining four items had very large total Medicare payments in 2000. The 16 items we reviewed represent more than $1.7 billion (26 percent) of $6.8 billion in total allowed charges for medical equipment and supplies in 2000.

The table below provides a description for each of the 16 codes reviewed. The methodology is provided as an appendix to this testimony.

Medicare Code	Description
A4253	Blood glucose test or reagent strips for home blood glucose monitor, per 50 strips
A4259	Lancets, per box of 100
A4323	Sterile saline irrigation solution, 1000 ml
B4035	Enteral feeding supply kit; pump fed, per day
E0135	Walker, folding (pickup), adjustable or fixed height
E0163	Commode chair, stationary, with fixed arms
E0178	Gel or gel-like pressure pad or cushion, nonpositioning
E0180	Pressure pad, alternating with pump
E0181	Pressure pad, alternating with pump, heavy duty
E0260	Hospital bed, semi-electric (head and foot adjustment), with any type side rails, with mattress
E0277	Powered pressure-reducing air mattress
E0570	Nebulizer, with compressor
E0730	TENS (transcutaneous and/or neuromuscular electrical nerve stimulators), four lead, larger area/multiple nerve stimulation

Medicare Code	Description
E0776	IV pole
K0001	Standard wheelchair
K0011	Standard-weight frame motorized/power wheelchair with programmable control parameters for speed adjustment, tremor dampening, acceleration control and braking

The results of our review are presented in the following table:

SUMMARY OF MEDICARE PRICES COMPARED TO VA, MEDICAID, RETAIL, AND FEHP PRICES FOR 16 ITEMS

Medicare code	Median Medicare price	Median VA price without markup	Percentage difference between Medicare and VA without markup	Median VA price with 67 percent markup	Percentage difference between Medicare and VA with 67 percent markup	Median Medicaid price	Percentage difference between Medicare and Medicaid	Median retail price	Percentage difference between Medicare and retail	Median FEHP price	Percentage difference between Medicare and FEHP
A4253	$38.32	$19.50	49.11	$32.57	15.01	$35.81	6.55	$42.42	−10.70	$36.75	4.10
A4259	12.68	8.69	31.47	14.51	−14.43	10.95	13.64	7.40	41.64	12.00	5.36
A4323	8.68	1.02	88.25	1.70	80.41	7.33	15.55	6.25	28.00	7.95	8.41
B4035	10.67	2.40	77.51	4.01	62.42	10.67	.....	9.05	15.18	11.30	−5.90
E0135	83.43	39.36	52.82	65.73	21.22	69.57	16.61	95.60	−14.59	73.42	12.00
E0163	109.74	32.30	70.57	53.94	50.85	89.16	18.75	112.50	−2.52	100.00	8.88
E0178	120.74	N/A	N/A	N/A	N/A	101.87	15.63	118.31	2.01	111.90	7.32
E0180	227.01	94.20	58.50	157.31	30.70	222.17	2.13	287.50	−26.65	210.20	7.40
E0181	251.58	71.00	71.78	118.57	52.87	230.40	8.42	242.05	3.79	231.65	7.92
E0260	1,754.55	762.10	56.56	1,272.71	27.46	1,359.10	22.54	1,608.91	8.30	1,397.65	20.34
E0277	7,933.91	5,297.50	33.23	8,846.83	−11.51	6,341.10	20.08	3,912.50	50.69	7,000.00	11.77
E0570	206.2	32.24	84.37	53.84	73.89	158.51	23.14	182.0	11.74	160.29	22.27
E0730	365.76	165.00	54.89	275.55	24.66	353.45	3.37	645.00	−76.35	334.39	8.58
E0776	142.45	50.25	64.72	83.92	41.09	108.62	23.75	39.10	72.55	116.71	18.07
K0001	570.68	127.72	77.62	213.29	62.63	456.12	20.07	533.50	6.52	530.00	7.13
K0011	5,270.30	2,767.64	47.49	4,621.96	12.30	4,912.16	6.80	5,347.83	–1.47	5,097.40	3.28

Sources: Centers for Medicare & Medicaid Services, Medicare Fee Schedules, January 2002; Department of Veterans Affairs (VA), Pharmacy Benefit Management, Drug & Pharmaceutical Prices, March 25, 2002; VA, National Acquisition Center, Federal Supply Schedule Contracts, March 2002; Office of Inspector General (OIG), Survey of State Medicaid Agencies, March 2002; OIG Survey of Medical Equipment Suppliers, March 2002; OIG Survey of Federal Employee Health Plans (FEHPs), March 2002.

Findings

For some of the items in our analysis, Medicare consistently paid more than the other payers we reviewed. For example, median prices from all four sources (VA, Medicaid agencies, FEHB Plans, and retail suppliers) were more than 10 percent lower than Medicare rates for 3 of the 16 items. These items were powered pressure-reducing air mattress, nebulizer with compressor, and IV pole. Additionally, three of the four sources had prices that were at least 10 percent less than Medicare for another four items. These items were lancets, sterile saline irrigation solution, walker, and semi-electric hospital bed. A more detailed discussion of the price comparisons follows:

Department of Veterans Affairs

Medicare's reimbursement amount was greater than the VA median price for 15 of the 16 items reviewed. We could not find a VA price for the remaining item. The VA median prices ranged from 31 to 88 percent less than the Medicare prices. Maximum potential total savings would be $958 million per year if Medicare were to adopt these median VA prices. In addition to comparing the Medicare price to the median VA price without a markup, we have compared it to the median VA price with a 67 percent markup. In the August 13, 1999 Federal Register, when CMS compared Medicare prices to median VA prices, they added a 67 percent markup to the VA prices. We used CMS' 67 percent figure since it was the only available data concerning a potential markup percentage. We did not verify or update the CMS markup percentage, nor do we advocate this as the appropriate markup to VA prices. We have presented the 67 percent markup price comparison solely to provide an example of possible savings, which take into account the distinction between Medicare as a payer and the VA as a purchaser of medical equipment and supplies. A mark up of 67 percent would result in potential savings of $440 million.

Medicaid Prices

The Medicare reimbursement was more than the Medicaid reimbursement for 15 of the16 items reviewed. Medicare reimbursed the same as Medicaid for the remaining item. Median Medicaid prices ranged from 0–24 percent less than Medicare prices. If Medicare had used the median Medicaid prices for reimbursement on these items, the program could have saved $193 million.

Federal Employee Health Plan Prices

Medicare reimbursed more than the FEHB Plans median price for all but one of the items reviewed. The FEHB Plans prices ranged from 3 to 22 percent lower for the 15 items with reimbursement rates lower than Medicare. If Medicare were to reimburse based on FEHB Plan median prices, the program could save $118 million.

Retail Prices

Medicare prices were more than the median retail price for 10 of the 16 items. These median prices ranged from to 2 to 73 percent less than the Medicare price for the item. Potential Medicare savings would reach $84 million if Medicare used median retail prices for reimbursement on these 16 items.

Competitive Bidding Demonstration Prices

I would also like to note that four of the items in our analysis (saline solution, enteral feeding supply kits, semi-electric hospital beds, and standard wheelchairs) have been, or are currently, in Medicare's competitive bidding demonstrations for DME, prosthetics, orthotics, and supplies. Competitive bid prices were 8 to 33 percent less than Medicare reimbursement rates for these four items.

INHERENT REASONABLENESS

CMS has certain authorities to control unreasonably high or low payment levels for medical equipment and supplies. Using the inherent reasonableness process, CMS is permitted to use other payment methodologies to align payment amounts with current market prices. Congress gave CMS added flexibility in making inherent reasonableness adjustments in the Balanced Budget Act of 1997. The law allows CMS to make inherent reasonableness adjustments, without formal rulemaking, as long as the annual adjustments are 15 percent or less. For these adjustments, CMS is required to describe in regulation the factors to be used in determining when payment amounts are not inherently reasonable and those factors to be considered when establishing reasonable payment amounts.

In 1998, CMS published an interim final rule revising the inherent reasonableness regulations. The DMERCs then surveyed retail prices for products they believed might have excessive Medicare payment rates. The DMERCs notified sup-

pliers that they proposed to adjust Medicare payments for eight products and solicited public comments. The medical equipment and supplies industry raised concerns about the proposed reductions, and CMS suspended them.

The CMS also attempted to use the inherent reasonableness process in August 1999 by issuing a proposed notice to replace current fee schedules and implement special payment limits for five items of DME and one prosthetic device. The CMS determined that Medicare reimbursement for the six items was grossly excessive relative to the amount paid by the VA, and therefore not inherently reasonable. The CMS increased the median VA wholesale prices by a mark up of 67 percent to make a valid comparison between Medicare and VA prices.

Because of concerns associated with the inherent reasonableness process, the Congress passed legislation in November 1999 prohibiting CMS from using its inherent reasonableness authority until a GAO report on the subject was issued, and a final rule has been published that responded to the GAO report and to public comments. The GAO report, issued in July 2000, found that there was sufficient evidence to indicate that Medicare overpays for most of the items identified by the DMERCs in 1998, and that the use of the inherent reasonableness process for some items was justified. For other items, GAO questioned the rigor that carriers used in their collection of pricing data. The GAO recommended that CMS define what grossly excessive or deficient prices were in the final rule on the inherent reasonableness process. It also recommended that CMS develop and implement a more structured and consistent data collection sampling and survey methodology for inherent reasonableness reviews. In addition, GAO recommended that CMS monitor patient access to products with reduced payments. To date, the final rule for inherent reasonableness has not been promulgated.

COMPETITIVE BIDDING

The Balanced Budget Act of 1997 authorizes CMS to enter into competitive bidding demonstrations for some categories of DME, prosthetics, orthotics and supplies. Using this authority, CMS has conducted multiple competitive bidding demonstrations with promising results.

In the first demonstration, CMS selected five categories of DME, prosthetics, orthotics and supplies for competitive bidding in Polk County, Florida. Payments under the first demonstration began on October 1, 1999 and were in effect through September 30, 2001. Medicare implemented a second round of competitive bidding in Polk County in October 2001 for four product categories. Payments under this demonstration will remain in effect through September 30, 2002. The CMS estimates savings for Medicare and Polk County beneficiaries of 17 percent ($1.3 million) annually as compared to payments that would have been incurred under the year 2000 Medicare fee schedules.

Medicare implemented an additional competitive bidding demonstration in San Antonio, Texas from February 1, 2001 through December 31, 2002 for five product categories. The CMS estimates 22 percent savings with this round of competitive bidding.

INVESTIGATIVE CASES

In addition to our audits and evaluations, the OIG has aggressively investigated individuals and entities that have defrauded our programs in this area. Between 1996 and 2001, our investigations led to 88 successful criminal prosecutions of DME suppliers. During this same period, there were 82 civil settlements or judgments imposed. Together, these criminal convictions and civil adjudications resulted in more than $277 million in restitution, fines and penalties being ordered by the courts. Also, during this time period, 166 exclusions were imposed on DME companies or their owners and employees.

I would like to highlight two of these cases for you today. The first case involved the misbranding of a SureStep glucose meter. The company submitted documents to the Food and Drug Administration (FDA) and marketed the SureStep glucose meter without disclosing two defects that led some users to become medically compromised. In this case, the equipment manufacturer was willing to risk the death of beneficiaries from the use of defective equipment because it could make so much money selling glucose monitoring strips for use with the meter. This company plead guilty to the misbranding allegation and paid a $30 million criminal fine in addition to a $30 million civil penalty. The second case involved one of the nation's largest suppliers of respiratory services. Allegations included submission of forged and falsified documents, self-qualifying of oxygen tests, double billing, claims for undelivered items, claims for deceased patients and inflated claims. A random sample of filed from one of the company's subsidiaries revealed a 95 percent error rate. The

company agreed to pay the government $17 million to resolve its liability under the False Claims Act for these allegations.

CONCLUSION

Mr. Chairman, over the years you have expressed concern that Medicare payments for many medical supplies remain excessive when compared to those of other payers. I know that you have worked diligently to safeguard taxpayer dollars and protect the Medicare program and its beneficiaries from fraud and abuse. We greatly appreciate your efforts. CMS also has made significant improvements over the years to this important benefit including consolidating claims processing, establishing supplier standards and requiring supplier applications. Competitive bidding also has shown promising initial results.

Our work on the 16 items, as well as our prior work, documents that Medicare pays too much for some medical equipment and supplies. We believe that fundamental reform is needed to ensure that Medicare and its beneficiaries pay a fair price. Fortunately, two promising reforms which we have long supported are already available for use. In fact, it is noteworthy that for nine items in our review, CMS has proposed reducing prices through the inherent reasonableness process or has used competitive bidding to actually lower prices. However, CMS needs to complete its inherent reasonableness regulation, and the Administration and the Congress need to work together to expand the competitive bidding provision beyond the demonstration phase.

Thank you for the opportunity to discuss these important issues. I will be happy to answer your questions.

APPENDIX A.—PRICE COMPARISONS FOR 16 MEDICAL EQUIPMENT AND SUPPLY ITEMS METHODOLOGY

For the items reviewed, we calculated the median price from each source (VA, Medicaid agencies, FEHB Plans, and retailers) and compared it to Medicare's median price. We then calculated the percentage difference between the Medicare price and the median prices of each of the four sources (i.e., we found the difference between the Medicare price and the other source's lower price, and divided the difference by the Medicare price). For those items where the Medicare price was higher than the source's price, we multiplied this percentage by the total Medicare payments for the item in 2000 to get an estimated annual dollar savings. We used the January 2002 Medicare fee schedules to determine the Medicare purchase prices for the 16 Medicare codes in our sample. Since fee schedule rates for the same codes differ among States, we calculated the median rate from the fee schedule rates for all 50 States, Puerto Rico, and the Virgin Islands.

For the seven codes in the capped rental payment category, we used the Medicare formula to calculate how much these items would cost if beneficiaries chose to own them. For all but one of the items, the least expensive purchase price is equal to 13 months of rental, and for the remaining item (motorized wheelchair) it is equal to 10 months of rental. Six codes in our sample are items that may be purchased new or used. In these cases, we used the fee schedule purchase price for new items. The remaining three codes in our sample are supplies that cannot be re-used and there is only one possible purchase price for these items in the fee schedule.

We also gathered information from past and current CMS competitive bidding demonstration projects in Polk County, Florida and San Antonio, Texas. We reviewed the list of items included in the demonstrations to determine if any of the 16 items we reviewed had competitive bid prices.

We sent a request to the VA's National Acquisition Center to provide us with current Federal Supply Schedule prices for equipment and supplies that matched the description of our 16 Medicare codes. The National Acquisition Center handles the largest combined contracting activity within the VA. The National Acquisition Center determined which vendor contracts might contain products that matched the descriptions for 14 of the codes, and sent us the contract containing prices. For the two remaining codes (A4253—blood glucose test strips and A4259—lancets), we obtained Federal Supply Schedule prices from the VA's Pharmacy Benefit Management website. From the available VA data, we identified items that we believed matched the descriptions of our Medicare codes.

We sent requests to 52 State Medicaid agencies and 58 fee-for-service FEHB Plans to provide current reimbursement prices for items matching the description of the 16 Medicare codes. We received responses from 40 Medicaid agencies and 30 FEHB Plans. Not all of the respondents could provide rates for every item.

Finally, for each of the 16 codes, we identified Medicare suppliers that received the highest payments for that particular code in 2000. For each code we obtained

retail prices from 10 suppliers. We asked suppliers how much it would cost to buy the item, in cash, including tax and delivery charges. For three of the 16 items—blood glucose test strips for home blood glucose monitors, lancets, and enteral feeding supply kits for use with pumps—we requested more than one price. Generally, blood glucose test strips are made to fit specific brands of equipment. Therefore, prior to calling suppliers, we identified two commonly-used brands of test strips. We then requested the prices of these two brands of test strips from suppliers. Blood glucose test strips and lancets are often sold through mail order which may result in different prices than retail prices. Therefore, we asked for the mail order as well as the retail price. For enteral feeding supply kits, we identified two supply kits billed under code B4035, and then we asked suppliers for the prices of both supply kits. In addition, the enteral feeding supply kits are covered by Medicare on a per day basis, while the prices we were quoted were per unit. In our analysis, we compared the per-unit price to Medicare's per-day price.

Senator HARKIN. Ms. Rehnquist, thank you very much. I did not know that timing clock was on. I wanted to give you plenty of time, but we will get into a discussion.

Again, let me just thank you and your whole office for really being diligent on this and doing it in a good time frame and not dragging it out for a long time.

Ms. REHNQUIST. Well, thank you.

Senator HARKIN. We really appreciate that very much. I went over the whole report. I just thought you did everything exemplary in terms of the investigation and bringing to light what we were paying on these items. So, again, I thank you and, through you, the staff that works for you.

Ms. REHNQUIST. They deserve a lot of the credit.

Senator HARKIN. Thank you.

STATEMENT OF LESLIE G. ARONOVITZ, DIRECTOR, HEALTH CARE, PROGRAM ADMINISTRATION AND INTEGRITY ISSUES, UNITED STATES GENERAL ACCOUNTING OFFICE

Senator HARKIN. Now we will turn to Ms. Aronovitz. Leslie Aronovitz is a Director of the Health Care Team for the GAO, the General Accounting Office. She received her bachelor's degree from the University of Georgia and her M.B.A. from the Boston University. Again, Ms. Aronovitz, your testimony will be made a part of the record in its entirety, but please proceed as you desire.

Ms. ARONOVITZ. Thank you, Mr. Chairman. I am pleased to be here today to discuss Medicare payment methods for medical equipment, supplies, and covered outpatient drugs.

You have heard from the Inspector General about the wide disparities between Medicare's payment rates and the prices paid by others such as the VA or even retail customers. In a similar vein, we reported last year on Medicare's policy of paying list price for covered outpatient drugs, while physicians and pharmacy suppliers could purchase them at substantial discounts—in one case as high as 86 percent off the list price.

To best understand how to begin fixing this problem, I would like to take a minute to review the context in which Medicare operates as a payer of health care services and products. This will help explain in part why effective solutions have been so elusive.

MEDICARE PAYMENT APPROACHES LACK FLEXIBILITY TO KEEP PACE WITH MARKET CHANGES

Medicare is a highly visible public program with certain obligations that may not be consistent with efficient business practices.

For example, CMS is constrained from acting swiftly to reprice services and products even when prevailing market rates suggest that payments should be modified. When making substantive changes, Medicare is generally required to obtain public input. While this minimizes the potential for actions to have unintended consequences, seeking and responding to public input from various provider and supplier groups has been a cumbersome and time consuming process which often takes years to make needed changes.

In addition, Medicare faces constraints on excluding qualified providers which is the leverage that purchasers typically use to make competition effective. Currently Medicare's method of paying for medical equipment and supplies is through fee schedules that remain tied to suppliers' historical charges rather than market prices. Similarly, Medicare's method of determining outpatient drug payments is based on list prices, not prices that other purchasers actually pay for the drugs.

Thus, neither method links Medicare payments to the marketplace, and that is one of our suggestions—that Medicare needs to have current price information, and information on actual transactions that occur in the marketplace. Add to this a process for revising rates that lacks the flexibility to make adjustments quickly, and you can see why Medicare has difficulty keeping pace with market changes.

BBA REFORMS SOUGHT TO IMPROVE MEDICARE'S ABILITY TO SET APPROPRIATE RATES

Even though the Balanced Budget Act of 1997 gave CMS—then HCFA—the authority to use a streamlined process to adjust payment rates for most medical equipment and supplies, CMS remains effectively precluded by the Congress from using this authority because of certain procedural steps that the Agency has not fulfilled. This authority is expected to be restored when CMS publishes final regulations establishing a streamlined process that includes sufficient steps for public notice and comment.

Under the BBA of 1997, Medicare does have the authority to conduct competitive bidding demonstrations for a limited number of items at a few locations. Two demonstrations thus far have involved suppliers competing for the right to supply certain items on the basis of quality and price. These demonstrations have reported savings without measurable problems in regards to beneficiary access.

PAST EFFORTS TO CORRECT INAPPROPRIATE PAYMENTS SUGGEST LESSONS FOR THE FUTURE

What we have learned from past efforts to lower Medicare's overly generous payments is that changes are most effectively implemented when the process used is rigorously defensible. Thus, lesson one is that payment changes need to be based on data-driven analyses of their potential impact on provider behavior and beneficiary access. This helps avoid one extreme of taking premature action based on external pressures and the other extreme of taking no action when it is clearly warranted.

Lesson two—which relates to the first lesson—is that CMS has not been well-positioned to collect and analyze data regarding cur-

rent market prices and the potential effects that price adjustments could have on suppliers and beneficiaries before the agency takes action. For example, information on Medicare claims from medical equipment and supplies is not specific enough to enable CMS to determine which products Medicare is actually paying for.

PREPARED STATEMENT

Lesson three is that the positive results achieved from the two competitive bidding demonstrations may be difficult to expand on a national scale. This is due to the labor-intensive outreach efforts in each of the two communities and the ongoing monitoring required in regards to beneficiary access and product quality. Despite this, the early success of competitive bidding demonstrations in Florida and Texas clearly shows that CMS can and should continue along this route.

Mr. Chairman, this concludes my prepared statement, and I will be happy to answer any questions that you have.

[The statement follows:]

PREPARED STATEMENT OF LESLIE G. ARONOVITZ

MEDICARE—CHALLENGES REMAIN IN SETTING PAYMENTS FOR MEDICAL EQUIPMENT AND SUPPLIES AND COVERED DRUGS

Mr. Chairman and Members of the Subcommittee: I am pleased to be here as you discuss Medicare payment methods related to durable medical equipment, prosthetics, orthotics, and supplies—products referred to in this statement as medical equipment and supplies—and covered outpatient drugs. Over the years, we and the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) have periodically reported that Medicare has paid higher than market rates for various medical equipment and supply items and often considerably higher than provider acquisition costs for Medicare-covered outpatient drugs.[1] Since the late 1980s, the Congress has enacted a series of legislative changes affecting payment methods and payment adjustment authority for medical equipment and supplies and outpatient drugs. However, the progress made in setting appropriate rates has been mixed, owing, in part, to various constraints faced by the agency responsible for administering Medicare—the Centers for Medicare and Medicaid Services (CMS), formerly called the Health Care Financing Administration (HCFA).[2]

In this regard, my remarks today will focus on: (1) Medicare's experience in setting payment rates for medical equipment and supplies and outpatient drugs; (2) certain changes designed to assist in setting payments for medical equipment and supplies and outpatient drugs incorporated in the Balanced Budget Act of 1997 (BBA);[3] and (3) lessons learned from efforts to improve the appropriateness of Medicare's payments. My comments are based primarily on our previously issued work.

In summary, because of the program's size, scope, and role as a public payer, Medicare has limited options to set and adjust payments for medical equipment and supplies and outpatient drugs. For example, in cases where Medicare is the dominant payer for a service or product, the program's share of the payments can distort the market, making reliance on market prices problematic. Medicare's method of paying for medical equipment and supplies is through fee schedules that remain tied to suppliers' historical charges to Medicare rather than market prices. Similarly, Medicare's method of determining outpatient drug payments is based on list prices, not prices that purchasers actually pay for the outpatient drugs. Medicare's payment approaches lack flexibility to keep pace with market changes, and as a result, Medicare often pays higher prices than other public payers for medical equipment and supplies and outpatient drugs.

Despite dramatic instances of wide disparities in market prices and Medicare's payment rates for medical equipment and supplies and outpatient drugs, Medicare

[1] A list of related GAO products is included at the end of this statement.

[2] This statement will refer to HCFA in discussing actions taken before the agency's name was officially changed on July 1, 2001.

[3] Pub. L. No. 105–33, 111 Stat. 251.

is not in a position to take prompt action. To lower unreasonably high payment rates, it must follow a lengthy and complicated regulatory process for making payment adjustments. The BBA gave HCFA authority to use a streamlined process to adjust payment rates for most medical equipment and supplies and outpatient drugs.[4] However, the agency's attempt to use this authority drew intense industry criticism, in part because the agency acted before it responded to public comment on how it would implement the authority. The Congress then prohibited use of either the original or streamlined processes until public comments are addressed and a final rule issued.[5] To date, a final rule has not been published, effectively precluding the use of the original or streamlined processes to adjust Medicare payment rates, where excessive. Nevertheless, the BBA also provided HCFA the authority to test an alternative to setting prices administratively.[6] This authority permitted HCFA to conduct demonstrations, for a limited number of items at a few locations, using competition to determine an appropriate payment for these items. In this process, suppliers competed for the right to supply certain items on the basis of quality and price. Two such demonstrations have reported savings without any measurable problems in beneficiary access.

Past efforts to lower Medicare's overly generous payments suggest several lessons. First, payment changes are most effectively implemented when the process used to set or adjust a rate is defensible. Medicare's size and impact on the nation's health care economy means that its payment methods and rate adjustments, no matter how reasonable, will face close scrutiny. As a result, the need for CMS to collect sufficient information on market prices and potential effects on suppliers and beneficiaries before taking action is paramount. A second lesson, related to the first, is that the information on Medicare claims for medical equipment and supplies is not specific enough to enable CMS to determine which products Medicare is actually paying for. Thus, the agency has difficulty trying to use market prices to set appropriate rates. A third lesson is that for the foreseeable future, CMS will have to continue to rely on fee schedules based on historical charges in setting payment rates for medical equipment and supply items. The recent demonstrations that set payments for items through competitive bidding were instructive, but the positive results achieved may be neither applicable nor practical on a wider scale for many products.

BACKGROUND

CMS, an agency within HHS, is responsible for much of the federal government's multi-billion-dollar payments for health care, primarily through the Medicare and Medicaid programs. Medicare—the nation's largest health insurance program—covers about 40 million elderly and disabled beneficiaries. Medicaid is a state-administered health insurance program, jointly funded by the federal and state governments, that covers eligible low-income individuals including children and their parents, and aged, blind, and disabled individuals. Each state administers its own program and determines—under broad federal guidelines—eligibility for, coverage of, and reimbursement for, specific services and items.

Most Medicare beneficiaries purchase part B insurance, which helps pay for certain physician, outpatient hospital, laboratory, and other services; medical supplies and durable medical equipment (such as oxygen, wheelchairs, hospital beds, and walkers); and certain outpatient drugs. Medicare part B pays for most medical equipment and supplies using a series of fee schedules. Medicare pays 80 percent, and the beneficiary pays the balance, of either the actual charge submitted by the supplier or the fee schedule amount, whichever is less. Generally, Medicare has a separate fee schedule for each state for most categories of items, and there are upper and lower limits on the allowable amounts that can be paid in different states to reduce variation in what Medicare pays for similar items in different parts of the country.

The fee schedules specify a Medicare-allowable payment amount for each of about 1,900 groups of products. Each product group is identified by a Healthcare Common Procedure Coding System (HCPCS) Level II code, and all products grouped under a code are intended to be items that are alike and serve a similar health care function. For example, one code (E1130) describes a standard wheelchair with fixed arms. Many different brands can be billed under this code, so long as they fit the basic description.

---

[4] BBA at § 4316, 111 Stat. 390 (codified at 42 U.S.C. § 1395u(b)(8) and (9) (Supp. III 1997)).

[5] Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. No. 106–113, App. F, § 223, 113 Stat. 1501, 1501 A–352 (to be codified at 42 U.S.C. 1395u(b)(8) (Supp. V 1999)).

[6] BBA at § 4318, 111 Stat. 392 (codified at 42 U.S.C. § 1395w–3 (Supp. III 1997)).

Medicare part B also covers roughly 450 outpatient drugs—generally those that cannot be self-administered and are related to physicians services, such as cancer chemotherapy, or are provided in conjunction with covered durable medical equipment, such as inhalation drugs used with a nebulizer.[7] In addition, Medicare part B covers selected immunizations and certain outpatient drugs that can be self-administered, such as blood clotting factors and some oral drugs used in association with cancer treatment and immunosuppressive therapy.

To administer Medicare part B fee-for-service claims, CMS contracts with insurance companies, referred to as carriers, who review and pay claims that have been submitted by physicians and other outpatient providers and suppliers. To ensure appropriate payment, carriers conduct claims reviews that determine, for example, whether the services claimed are covered by Medicare, are reasonable and necessary, and have been billed with the proper codes.

PAYMENT APPROACHES LACK FLEXIBILITY TO KEEP PACE WITH MARKET CHANGES

Medicare's size and complexity make it extremely challenging to develop payment methods that prudently reimburse providers while promoting beneficiary access to items and services. As Medicare's steward, CMS cannot passively accept what providers want to charge the program. However, because of its size, Medicare profoundly influences health care markets. Medicare is often the dominant payer for services and products, and in such cases, it cannot rely on market prices to determine appropriate payment amounts because Medicare's share of payments distorts the market. In addition, Medicare has had difficulty relying on competition to determine prices. Because of constraints on excluding any qualified provider from participating in the program, Medicare traditionally includes all such providers who want to participate. Finding ways of encouraging competition without excluding some providers—a normal leverage that purchasers use to make competition work—has been problematic. As a result, Medicare has had to administratively set payment amounts for thousands of services and items, trying to do so in ways that encourage efficient delivery, while ensuring beneficiary access to them.

Adding to the complexity of setting payment amounts is Medicare's status as a highly visible public program with certain obligations that may not be consistent with efficient business practices. For example, CMS is constrained from acting swiftly to reprice services and supplies even when prevailing market rates suggest that payments should be modified. When making substantive changes, Medicare's enabling legislation generally requires public input. This minimizes the potential for actions to have unintended consequences. However, seeking and responding to public input from various provider and supplier groups can be a time-consuming process that can sometimes thwart efficient program management.

Prior to 1987, Medicare payments for medical equipment and supplies were based on supplier charges, subject to some limitations. As part of their responsibilities to administer Medicare claims, individual Medicare carriers raised or lowered payments to suppliers in their local areas to align them with market prices. When carriers sought to adjust payments on this basis, they employed a process that involved gathering relevant pricing data from local area markets, determining new payment levels on the basis of the price information obtained, and notifying area suppliers of the changes. Although HCFA monitored carriers' performance in carrying out these steps, it did not evaluate the appropriateness of the new payment levels established.

In 1987, the Congress and HCFA began the process of moving the Medicare program from paying on the basis of individual providers' charges for medical equipment and supplies and covered outpatient drugs, to developing payment methods intended to pay more prudently through use of program-determined amounts. Specifically, the Congress introduced fee schedules for medical equipment and supplies in 1987.[8] Statewide fees were determined on the basis of average supplier charges on Medicare claims allowed in each state in 1986 and 1987, and were updated for inflation in some years.[9] However, the agency lacked mechanisms to otherwise adjust

[7] A nebulizer is a device driven by a compressed air machine that allows the patient to take medicine in the form of a mist or wet aerosol.

[8] Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100–203, § 4062, 101 Stat. 1330, 1330–101 (codified at 42 U.S.C. § 1395m (1988)). Certain medical equipment and supply items not originally on a fee schedule were added later—for example, surgical dressings, were added by the Omnibus Budget Reconciliation Act of 1993 Pub. L. No. 103–66, § 13544(b), 107 Stat. 312, 589 (codified at 42 U.S.C. § 1395m(i) (1994)).

[9] Prior to 1998, these fees were adjusted each year using formulas tied to the Consumer Price Index. No update was provided from 1998 through 2000 or in 2002, although updates were provided in 2001. 42 U.S.C. § 1395m(a)(14) (Supp. IV 1998); Medicare, Medicaid and SCHIP Bal-

fees to reflect marketplace changes. As a result, disparities between fee schedule amounts and market prices developed over time, and Medicare significantly overpaid for some medical equipment and supplies.

In recent years, we and the HHS OIG reported on instances where Medicare payments for certain medical equipment and supplies and outpatient drugs were excessive compared with retail and other prices. One notable example of excessive Medicare payments is included in our 1995 report on surgical dressings.[10] We estimated that Medicare could have saved almost $20 million in 1995 if it had paid the lowest wholesale prices available in a national catalog for 44 types of surgical dressings. Although Medicare's fee schedule for surgical dressings was based on medians of retail prices found in supply catalogs when the schedule was set, Medicare's statute did not permit HCFA to lower the fee schedule when retail prices for dressings decreased.[11]

Another instance of excessive Medicare payment was for home oxygen equipment and supplies provided to patients with pulmonary insufficiency. Medicare fee schedule allowances for home oxygen were significantly higher than the rates paid for almost identical services by the Department of Veterans Affairs (VA), which in fiscal year 1995 paid for home oxygen benefits for over 23,000 patients. In 1997, we estimated that Medicare could have saved over $500 million in fiscal year 1996 if it had paid rates for home oxygen comparable to those paid by VA.[12]

Medicare's payments for outpatient drugs have been similarly excessive, although the methodology used to determine payment amounts is somewhat different and attempts to tie Medicare's payments to market prices. In 1989, the Congress required that physician services be paid based on fee schedules beginning in 1992.[13] The fee schedules developed by HCFA to comply with this requirement provided for all outpatient drugs furnished to Medicare beneficiaries not paid on a cost or prospective payment basis to be paid based on the lower of the estimated acquisition cost or the national average wholesale price (AWP).[14] Manufacturers report AWPs to organizations that publish them in drug price compendia, which are typically updated annually, and Medicare carriers base providers' payments on these published AWPs.

In concept, such a payment method has the potential to be market-based and self-adjusting. The reality is, however, that AWP is neither an average nor a price that wholesalers charge. Because the term AWP is not defined in law or regulation, there are no requirements or conventions that AWP reflect the price of any actual sale of drugs by a manufacturer. Given the latitude manufacturers have in setting AWPs, Medicare's payments are often not related to market prices that physicians and suppliers actually pay for the products.

A June 1997 House Budget Committee report accompanying the bill that became the BBA, in explaining the reason for specifying a 5-percent reduction from AWP, cited a report by the HHS OIG regarding Medicare payments for outpatient drugs.[15] Among the OIG findings were that Medicare payments ranged from 20 percent to nearly 1,000 percent of certain oncology drugs' commercially available prices.

Our recent work found that Medicare payments in 2001 for part B-covered outpatient drugs remained significantly higher than prices widely available to physicians and pharmacy suppliers.[16] For example, most physician-administered drugs had widely available discounts ranging from 13 to 34 percent below AWP. Two other

---

anced Budget Refinement Act of 1999, Pub. L. No. 106–113, App. F, § 228, 113 Stat. 1501, 1501A–356; and Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. No. 106–554, App. F, § 425, 114 Stat. 2763, 2763A–519 (to be codified at 42 U.S.C. § 1395m(a)(14)).

[10] U.S. General Accounting Office, Medicare: Excessive Payments for Medical Supplies Continue Despite Improvements, GAO/HEHS–95–171 (Washington, D.C.: Aug. 8, 1995).

[11] Authority to adjust payment rates that were excessive did not extend to surgical dressings and certain other medical supplies at that time. The BBA extended the authority to adjust rates for any payments under part B that are excessive. BBA at § 4316, sec. 1842(b)(8)(A)(i)(I), 111 Stat. 390 (changing "application of this subsection" to "application of this part)." Clarifying this broadened scope, "application of this part" was later changed to "application of this title to payment under this part." Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. No. 106–113, App. F, § 223(c), 113 Stat. 1501, 1501A–353.

[12] The savings estimate includes adding a 30-percent adjustment to VA payment rates to account for differences between the Medicare and VA programs. See U.S. General Accounting Office, Medicare: Comparative Information on Medicare and VA Patients, Services, and Payment Rates for Home Oxygen, GAO/HEHS–97–151R (Washington, D.C.: June 6, 1997).

[13] Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101–239, § 6102, 103 Stat. 2106, 2169 (codified at 42 U.S.C. § 1395w–4 (Supp. I 1989)).

[14] 56 Fed. Reg. 59,502, 59,507 (Nov. 25, 1991).

[15] H.R. Rep. No. 105–149, at 1354 (1997).

[16] U.S. General Accounting Office, Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost, GAO–01–1118 (Washington, D.C.: Sept. 21, 2001).

physician-administered drugs had discounts of 65 and 86 percent. Pharmacy suppliers—the predominant billers for 10 of the high-expenditure and high-volume drugs we analyzed—also purchased drugs at prices considerably lower than Medicare payments. For example, two inhalation drugs accounting for most of Medicare payments to pharmacy suppliers had widely available discounts averaging 78 percent and 85 percent from AWP.

BBA REFORMS SOUGHT TO IMPROVE MEDICARE'S ABILITY TO SET APPROPRIATE RATES

Despite such dramatic illustrations of disparities between Medicare payments and prices widely available to others acquiring medical equipment and supplies and covered outpatient drugs, Medicare has not had the tools to respond quickly in such instances. Carriers used to adjust payment amounts as part of their responsibility to appropriately pay Medicare claims, but in 1987, the Congress effectively prohibited use of this process to lower Medicare payment rates until 1991.[17] In 1988, the Congress required use of a more formal "inherent reasonableness" process that could be accomplished only by HCFA, not by the carriers.[18] In other reports, we have described this process as slow and cumbersome and have noted that it is not available for some items, such as surgical supplies.[19] Since 1991, when HCFA was first permitted to use the inherent reasonableness process to adjust payments for medical equipment and supplies, it successfully did so only once—for blood glucose monitors—and in that instance took almost 3 years to adjust the maximum allowable Medicare payment from $185.79 to $58.71.

In 1997, in response to concerns about HCFA's difficulties in adjusting payment rates determined to be excessive, the Congress included a provision in the BBA that gave HCFA authority to use a streamlined inherent reasonableness process to adjust payments for medical equipment and supplies and covered outpatient drugs by up to 15 percent a year.[20] Subsequent legislation required that a final regulation taking into account public comments be published before the agency could use any inherent reasonableness authority. Because the agency has not issued the final regulation, it cannot adjust Medicare's fee schedules to respond to market price information. The BBA also provided HCFA with opportunities to test an alternative to setting rates administratively that could be more responsive to market prices.[21] This alternative is competitive bidding—a process allowing suppliers to compete for the right to supply their products on the basis of established criteria, such as quality and price.[22]

STREAMLINED PROCESS TO ADJUST FEES NEEDS FURTHER REGULATORY ACTION TO BE IMPLEMENTED

The BBA gave HCFA authority to use a streamlined inherent reasonableness process for part B services (excluding physician's services). Under this authority, HCFA can adjust payments by up to 15 percent per year using a streamlined process, or can use its original process with formal notice and comment to make larger adjustments. In January 1998, the agency published an "interim final rule with comment period" for the streamlined inherent reasonableness process that became effective 60 days after it was published.[23] This was a departure from the usual practice of first responding to public comments before issuing a final regulation.

Under the interim final rule, HCFA delegated authority to use the streamlined process to the Medicare carriers that process claims for medical equipment and supplies, with final action on payment adjustments to be approved by the agency. The

---

[17] Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100–203, § 4062(b), 101 Stat. 1330, 1330–100.

[18] Medicare Catastrophic Coverage Act of 1988, Pub. L. No. 100–360, § 411(g)(1)(B)(xiii), 102 Stat. 683, 782. These procedures were previously applicable only to any inherent reasonableness review with respect to physician services. 42 U.S.C. 1395m(a)(10)(B) (1988).

[19] Changing an unreasonable payment level required, among other things, a formal notice-and-comment rulemaking process that involved the HCFA Administrator, the Secretary of Health and Human Services, and the Director of the Office of Management and Budget (OMB). U.S. General Accounting Office, Medicare Payments: Use of Revised "Inherent Reasonableness" Process Generally Appropriate, GAO/HEHS–00–79 (Washington, D.C.: July 5, 2000) and GAO/HEHS–95–171.

[20] BBA at § 4316, 111 Stat. 251, 390.

[21] BBA at § 4319, 111 Stat. 251, 392. (Codified at 42 U.S.C. § 1395w–4 (Supp. III 1997).

[22] In the competitive bidding demonstration projects authorized under BBA, Medicare part B items and services (other than physician services) were furnished under competitively awarded contracts. For each demonstration product or service, the prices bid by winning suppliers were used to determine the competitively bid fee schedule price.

[23] 63 *Fed. Reg.* 687 (Jan. 7, 1998). In this interim final rule, HCFA committed to having a notice and comment period for any payment adjustments, even through the streamlined process.

carriers attempted to lower maximum payment rates for eight groups of products, gathering information on retail prices through surveys conducted in at least 16 states. In September 1998, the carriers notified suppliers of proposed adjustments for eight groups of products and solicited comments. Industry groups representing various medical equipment and supply manufacturers and suppliers expressed serious concerns about how the inherent reasonableness process was implemented and whether the surveys were conducted properly. The Congress requested that we review the appropriateness of implementing the streamlined inherent reasonableness authority through an interim final rule and the soundness of the carriers' surveys. Pending the results of our review, HCFA suspended the carrier-proposed payment reductions in March 1999.

In November 1999, the Congress passed legislation prohibiting HCFA or the carriers from using any inherent reasonableness authority until we issued our report and the agency issued a final rule taking into account our findings and public comment.[24] In our July 2000 report, we concluded that, while the carriers could have conducted their surveys more rigorously, the surveys and other evidence sufficiently justified the carriers' proposed payment reductions for five of eight product groups.[25] In our report, we recommended that HCFA clarify criteria for using its inherent reasonableness authority, strengthen agency or carrier survey methodology in the future, collect additional data on prices for the other three product groups before adjusting their payment amounts, and monitor beneficiary access after any payment changes. Although our report is almost 2 years old, CMS has not issued a final regulation that would allow it to use either its streamlined or original inherent reasonableness processes to adjust Medicare payment amounts for part B supplier-billed services. Thus, the agency lacks a tool to adjust its fee schedules, short of statutory changes.

BBA PROVISIONS AUTHORIZED COMPETITIVE BIDDING DEMONSTRATION PROJECTS

In order to experiment with other ways of setting Medicare's payments for medical equipment and supplies and outpatient drugs, the BBA provided authority for HCFA to conduct demonstration projects using competitive bidding and to include home oxygen in at least one of the demonstrations.[26] Evidence from two competitive bidding projects suggests that, for most of the items selected, competition might provide a tool that facilitates setting more appropriate payment rates and result in program savings.

In its first competitive bidding demonstration, conducted in Polk County, Florida, HCFA set rates for oxygen, hospital beds, surgical dressings, enteral nutrition and supplies, and urological supplies through competitive bidding. HCFA reported that the new rates set by this competitive process in the Florida demonstration saved Medicare an average of 17 percent on the cost of these medical equipment and supply items without compromising beneficiary access to these items.[27]

In a second demonstration in San Antonio, Texas, the agency included oxygen; hospital beds; manual wheelchairs; noncustomized orthotic devices, including "off-the-shelf" items such as braces and splints; and albuterol sulfate and other nebulizer drugs. Preliminary CMS information on the San Antonio competitive bidding demonstration identified an average savings of 20 percent, without any negative effects on beneficiary access.

PAST EFFORTS TO CORRECT INAPPROPRIATE PAYMENTS SUGGEST LESSONS FOR THE FUTURE

Whether attempting to adjust payments administratively or through competitive bidding, CMS can only be effective if it has a defensible process for doing so and accurate information upon which to base action. Any change to Medicare's payments, particularly a reduction in fees for medical equipment and supplies or covered outpatient drugs, should be accompanied by an ongoing assessment of whether the new payments adequately support Medicare beneficiaries' access to such items and services and properly reimburse providers and suppliers. Such monitoring needs to examine current experience so that prompt fee adjustments can be made if access problems are found.

---

[24] Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, Pub. L. No. 106–113, App. F, § 223, 113 Stat. 1501, 1501A–352 (signed into law January 29, 1999).

[25] GAO/HEHS–00–79.

[26] BBA at § 4219, 111 Stat. 392. The BBA at 4552(a), 111 Stat. 459, also reduced home oxygen payment amounts by 25 percent effective January 1, 1998, and an additional 5 percent effective January 1, 1999.

[27] Medicare program savings did not occur in all product categories; there were higher prices for surgical dressings, one of five product categories in the demonstration.

Efforts to lower excessive payment rates through the inherent reasonableness process illustrate the difficulties CMS has in making even minor adjustments, as the agency's actions can have wide ramifications for providers, suppliers, and beneficiaries. When HCFA tried to use its streamlined inherent reasonableness authority in 1998 to reduce payment rates for various medical equipment and supply items and outpatient drugs, it attempted to take action before responding to public comment, thereby leaving the effort open to criticism. In addition, we concluded that the carriers' survey methodology was not rigorous enough to provide a basis to adjust fees nationally for all of the products under review.

What the agency lacked was sufficient information on market prices. Such information, along with current local, as well as national, data on beneficiaries' use of services and program expenditures, is key to setting rates administratively. Because HCFA did not have reliable acquisition cost information, its carriers engaged in a very labor-intensive information-gathering effort.

One major problem CMS has when going to the marketplace to collect information is that it cannot determine the specific products Medicare is paying for when carriers process claims for medical equipment and supplies. Carriers pay claims on the basis of billing codes indicating that the supplied items belong to a particular product group. These groups can cover a broad range of product types, quality, and market prices. As a result, products that differ widely in properties, use, performance, and price are billed under the same code and the program pays the same amount. For example, we reported in 1998 that catheters belonging to a single product category varied in type and price, from about $1 to $18, with Medicare's maximum fee payments ranging across states from $9.95 to $11.70.[28] However, HCFA had no information on which catheters were being provided to beneficiaries.

To address the problem of insufficient specificity, we recommended in the 1998 report that suppliers be required to include universal product numbers (UPN) as well as current billing codes on claims. UPNs and associated bar codes are increasingly used to identify specific medical equipment and supplies, similar to the way universal product codes are used in supermarkets. Manufacturers can use bar codes for each product to identify characteristics such as the manufacturer, product type, model, size, and unit of packaging. Using UPNs—or some other mechanism—incorporated into claim forms to bring more specificity to what is provided to beneficiaries could help CMS better determine appropriate payments.

Under provisions in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), HHS has adopted standards for coding medical services, procedures, and equipment and supplies.[29] These provisions were aimed at simplifying data reporting and claims processing requirements across all public and private payers. Under the standards, HCPCS Level II was designated as the code set for medical equipment and supplies. Its limitation in specificity argues for evaluating whether the current code set can be adjusted to better distinguish between various products currently grouped within a single HCPCS Level II code.

Lack of specificity has been a similar problem for the codes used to define inpatient hospital procedures. The HIPAA standard code set for reporting hospital inpatient procedures is the International Classification of Disease, 9th Edition, Clinical Modification, Volume 3 (ICD–9 CM Vol. 3). The inadequacy of this code set is widely recognized, as it lacks both the specificity to accurately identify many key aspects of medical procedures as well as the capacity to expand in order to appropriately incorporate codes in response to new technology. In fact, HHS recognized that in adopting the ICD–9-CM Vol. 3 as a HIPAA standard, the agency would need to replace it, given the code set's limitations. As a consequence, CMS plans to implement a new code set, the International Classification of Disease, 10th Edition, Procedural Coding System (10 PCS), which would provide much greater specificity.

Our work on payments for covered outpatient drugs, which identified strategies used by other payers to obtain prices closer to acquisition costs, underscores the value of accurate information for determining appropriate payments. For example, the VA uses the leverage of federal purchasers to secure verifiable information on actual market transactions by private purchasers—specifically, the prices that drug manufacturers charge their "most-favored" private customers. To enable the VA to determine the most-favored-customer price, by statute, manufacturers who wish to sell their products to the federal agencies involved are required to provide information on price discounts and rebates offered to domestic customers and the terms and conditions involved, such as length of contract periods and ordering and delivery

[28] U.S. General Accounting Office, Medicare: Need to Overhaul Costly Payment System for Medical Equipment and Supplies, GAO/HEHS–98–102 (Washington, D.C.: May 12, 1998).

[29] Pub. L. No. 104–191, § 262(a), § 1173(c), 110 Stat. 1936, 2025.

practices.[30] The manufacturers provide this information and agree to offer the VA and other government purchasers drugs at these prices, subject to VA audit of their records,[31] in order to have state Medicaid programs cover their drugs.

This type of information could be helpful in setting payment amounts for certain Medicare drugs. It is already available to CMS, but for use only in the Medicaid—not the Medicare—program.[32] With congressional approval, CMS could use the information provided to Medicaid to determine appropriate prices for Medicare that would be based on actual prices being paid in the market. One key step would be to determine the formula to use to calculate payments based on the price data. Most likely, Medicare would not set payments to match the prices paid by most favored customers but would need to pay closer to average market prices to ensure access for all beneficiaries and adequate payments to providers.

Results from the competitive bidding demonstrations suggest that competition can also serve as a tool to obtain more appropriate prices for medical equipment and supplies and outpatient drugs. By competing a small number of products and limiting the geographic area of competition, CMS took steps to manage the process, which included monitoring of beneficiary access and product quality. In its fiscal year 2003 budget, the Administration proposed expanding competitive bidding for medical equipment and supplies nationally, which it estimates could save $240 million in fiscal year 2003 and $5 billion over 10 years.

The Administration's expansion proposal to translate these limited demonstrations into a competition involving a larger number of products nationally would be a substantial undertaking and may not be practical or appropriate for all products. CMS would require new authority to begin to use competitive bidding outside of a demonstration. A key element to the new authority would be the extent to which and the basis whereby providers could be excluded from Medicare. While Medicare normally allows any qualified provider to participate in the program, competitive bidding may be most effective only by limiting the number of providers or suppliers who could provide items or services. For example, in the Polk County demonstration, only 16 out of the 30 bidders were selected to participate. Limiting the number of participating suppliers obviously has an effect on both beneficiaries and suppliers. While provider participation is not an entitlement, the effects of exclusion—in terms of numbers of providers and the volume of services affected—need to be identified and assessed. Similarly, for some products, who the provider is may be of little consequence for the beneficiary, but for others, maintaining greater beneficiary choice and direct access to the provider could be important.

Whether payment rates are set or adjusted through competitive bidding or administrative fee-setting, monitoring to ensure that beneficiaries continue to have access to the items or services is a critical component of such efforts. For example, when the Congress reduced Medicare home oxygen payment rates by 25 percent effective January 1, 1998, and an additional 5 percent effective January 1, 1999, it wanted assurance that beneficiaries could continue to receive satisfactory service.[33] To evaluate the impact of the home oxygen payment reduction on access and quality, the BBA required studies conducted by us and HHS.[34] Neither study found any sig-

---

[30] 38 U.S.C. § 8126 (1994).

[31] The VA negotiates prices for and purchases medical equipment, supplies, and drugs through the Federal Supply Schedule. Federal Supply Schedule prices are available to any federal agency that directly procures pharmaceuticals or medical equipment and supplies, including VA medical centers, the Department of Defense, the Bureau of Prisons, the Public Health Service, and other designated entities such as the District of Columbia, U.S. territorial governments, the Indian Health Service, and some state veterans homes.

[32] Under a provision of the Omnibus Budget Reconciliation Act of 1990 (OBRA), state Medicaid programs receive rebates from manufacturers based on either the manufacturer's "best price" to a private purchaser or the average price (including cash discounts and other price reductions) paid to drug manufacturers by U.S. wholesalers for certain drugs. In order to have their drugs covered by Medicaid, manufacturers must be willing to provide the rebate and price information to calculate it. § 1927 of the Social Security Act, added by OBRA 1990, Public Law 101–508, § 4401, 104 Stat. 1388, 1388–143 (1990) (classified to 42 U.S.C. Sec. 1396r–8).

[33] For beneficiaries who receive oxygen at home, Medicare part B pays suppliers a fixed monthly fee per beneficiary that covers a stationary, home-based oxygen unit and all related services and supplies, such as tank refills. There is a separate fixed monthly fee for a portable unit, if one is prescribed. Medicare's oxygen payment method is called "modality neutral" because the payment rate is the same regardless of the type of oxygen delivery system prescribed, i.e. compressed gas, liquid oxygen, or oxygen concentrator.

[34] U.S. General Accounting Office, Medicare: Access to Home Oxygen Largely Unchanged; Closer HCFA Monitoring Needed, GAO/HEHS–99–56 (Washington, D.C.: Apr. 5, 1999) and Rebecca Olson, Carolyn Harper, Stephanie Lui, and others. Report on Peer Review Evaluation of Home Oxygen Equipment. California Medical Review, Inc. (San Francisco, Calif.: Sept. 30,

Continued

nificant access problems with the payment reduction. In addition, home oxygen was included in both competitive bidding demonstrations, and through those demonstrations, prices were reduced further. HCFA estimated that Medicare's home oxygen payments were reduced by 16 percent in the Polk County demonstration, without beneficiary access problems. Such monitoring is important, not just when required by statute but as part of an ongoing effort to ensure the Medicare program is effectively serving its beneficiaries.

Unfortunately, such studies to review the effects of payment reductions on access are the exception. As we have reported before, CMS has not been able to generate data that are timely, accurate, and useful on payment and service trends essential to effective program monitoring.[35] One of the principal lessons to be drawn from the many BBA payment reforms is that newly implemented policies need a thorough assessment of their effects. Policy changes, particularly those that constrain payment, almost inevitably spark calls for revisions. Considerations of such revisions need to be based on sufficient information so that, at one extreme, policies are not unduly affected by external pressures and premature conclusions as to their impact, and at the other extreme, policies do not remain static when change is clearly warranted.[36] CMS has not been well-positioned to collect and analyze data regarding beneficiaries' use of services—information that is essential to managing the program effectively.[37] This year's 5.4 percent reduction of physicians' fees from what was paid in 2001 raised concerns about beneficiaries' access. While prior information available on physicians' willingness to see Medicare beneficiaries did not indicate access problems, this information is somewhat dated.[38] Informed decisions about appropriate payment rates and rate changes cannot be made unless policymakers have detailed and recent data on beneficiaries' access to needed services.

Mr. Chairman, this concludes my prepared remarks. I will be happy to answer any questions you or the Subcommittee Members may have.

Contact and Acknowledgments For further information regarding this testimony, please contact me at (312) 220–7600. Sheila Avruch, Hannah Fein, Sandra Gove, Joy Kraybill, and Craig Winslow made contributions to this statement.

RELATED GAO PRODUCTS

Medicare Outpatient Drugs: Program Payments Should Better Reflect Market Prices. GAO–02–531T. Washington, D.C.: March 14, 2002.

Medicare Physician Payments: Spending Targets Encourage Fiscal Discipline, Modifications Could Stabilize Fees. GAO–02–441T. Washington, D.C.: February 14, 2002.

Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost. GAO–01–1118. Washington, D.C.: September 21, 2001.

Medicare Part B Drugs: Program Payments Should Reflect Market Prices. GAO–01–1142T. Washington, D.C.: September 21, 2001.

Medicare Management: CMS Faces Challenges to Sustain Progress and Address Weaknesses. GAO–01–817. Washington, D.C.: July 31, 2001.

DOD and VA Pharmacy: Progress and Remaining Challenges in Jointly Buying and Mailing Out Drugs. GAO–01–588. Washington, D.C.: May 25, 2001.

Medicare Payments: Use of Revised "Inherent Reasonableness" Process Generally Appropriate. GAO/HEHS–00–79. Washington, D.C.: July 5, 2000.

Balanced Budget Act: Any Proposed Fee-for-Service Payment Modifications Need Thorough Evaluation. GAO/T–HEHS–99–139. Washington, D.C.: June 10, 1999.

Medicare: Need to Overhaul Costly Payment System for Medical Equipment and Supplies. GAO/HEHS–98–102. Washington, D.C.: May 12, 1998.

Medicare: Access to Home Oxygen Largely Unchanged; Closer HCFA Monitoring Needed. GAO/HEHS–99–56. Washington, D.C.: April 5, 1999.

2000). This HHS study analyzed 1996 and 1998 claims data to calculate the number of Medicare oxygen prescriptions, and also conducted 1999 surveys of physicians, suppliers, and beneficiaries.

[35] U.S. General Accounting Office, Major Management Challenges and Program Risks: Department of Health and Human Services, GAO–01–247 (Washington, D.C.: Jan. 2001).

[36] U.S. General Accounting Office, Balanced Budget Act: Any Proposed Fee-for-Service Payment Modifications Need Thorough Evaluation, GAO/T–HEHS–99–139 (Washington, D.C.: June 10, 1999).

[37] U.S.General Accounting Office, Medicare: HCFA Faces Challenges to Control Improper Payments, GAO/T–HEHS–00–74, (Washington, D.C.: Mar. 9, 2000).

[38] 9U.S. General Accounting Office, Medicare Physician Payments: Spending Targets Encourage Fiscal Discipline, Modifications Could Stabilize Fees, GAO–02–441T, (Washington, D.C.: Feb. 14, 2002).

Medicare: Comparative Information on Medicare and VA Patients, Services, and Payment Rates for Home Oxygen. GAO/HEHS–97–151R. Washington, D.C.: June 6, 1997.

Medicare: Excessive Payments for Medical Supplies Continue Despite Improvements. GAO/HEHS–95–171. Washington, D.C.: August 8, 1995.

STATEMENT OF THOMAS A. SCULLY, ADMINISTRATOR, CENTERS FOR MEDICARE AND MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Senator HARKIN. Thank you, Ms. Aronovitz. I do have some questions about this.

Next we turn to Mr. Tom Scully, the Administrator for the Centers for Medicare and Medicaid Services, formerly known as HCFA. Prior to this assignment, Mr. Scully was President of the Federation of American Health Systems representing for-profit hospital systems. Mr. Scully is also a former senior official with the OMB in the first Bush administration.

Welcome to the committee, Mr. Scully. Your statement will be made a part of the record in its entirety, and again please proceed as you so desire.

Mr. SCULLY. Chairman Harkin and Senator Murray, thank you for inviting me to discuss Part B payments for medical supplies today.

Mr. Chairman, I want to thank you in particular for pushing us aggressively to move forward on the inherent reasonableness regulation. This is a high priority of mine. I can assure you we have been working for months to get this regulation out, and as I have said repeatedly in the last couple of days in the press, you are totally right on this issue and we completely agree with you.

Senator HARKIN. I appreciate that.

Mr. SCULLY. I also want to thank Janet Rehnquist, the Inspector General, a far more distinguished member of the University of Virginia 1979 graduating class than I am, by the way.

MEDICARE PROGRAM

Senator HARKIN. You were both in the same class?

Mr. SCULLY. Same class. Hard to believe. She tries not to admit that for the most part.

I want to thank her for the IG's assistance in helping us to identify areas where we can improve our payment process and clearly save seniors money. Saving the Medicare program money is important, but what a lot of people forget, I think, is that not only does part of this money go in the premiums for seniors, but also co-payments. So, every dollar we ever pay for these supplies is more money coming out of seniors' pockets.

I would also note that not only for this issue—and I know Leslie's testimony talked a little about AWP for drugs, which is a very similar parallel issue—we are also overpaying—and that we propose to fix.

But all across the board, since I have come to CMS, one of my general approaches has been to try to find places where we either overpay or underpay for services. One of the first things I did is I hired two Wall Street analysts to put out reports on the basic industry sectors. Basically we deal with a lot of people, hospitals, nursing homes, managed care plans, DME providers. They're all

giant Government contractors, and I think it is the Government's role to figure out what their appropriate margins are. We believe people should make appropriate margins when they are Government contractors, but they should not make too much, they should not make too little.

I would note that we put out fairly detailed reports on managed care about 4 months ago, on nursing facilities about 2 months ago, on hospitals last month. We are actually going to have one out on home health payments which a lot of these issues revolve around, hopefully by the end of this week. The goal here is to identify when industries are overpaid, underpaid, whether their margins are too low or too high what is essentially Government contract business.

Switching back to the issue at hand today, we have a number of potential tools available to make sure the beneficiaries get the care they deserve and are not overpaying for these types of supplies. It is hard for me to see how anybody can argue with the concept that Medicare should be paying inherently reasonable prices for these supplies. So, we are determined to get this out.

Are there places where we not only—clearly the attention is where we overpay. There are some where arguably we underpay, and I have gotten hundreds of e-mails, for instance, on ostomy supplies in the last few weeks. We are looking into that. I think there are probably far more places where we overpay than underpay, but I think inherent reasonableness can clearly be used in both directions if there are places where we are underpaying for historical reasons.

The process in the past has been incredibly cumbersome. It has also been, obviously, very difficult politically. It was so cumbersome that in the BBA in 1997, Congress tried to streamline the inherent reasonableness process. In January of 1998, HCFA, now CMS, published an interim final rule implementing the inherent reasonableness process in the BBA in which we compared a lot of the payments that we are making to the VA and other public payors and found that we were paying too much. And we proposed lowering the payments for many items. Our durable medical equipment carriers similarly proposed lowering payments for additional items, which again lowers co-payments and premiums for seniors.

The medical equipment industry reacted pretty strongly to these proposals, and in response, the Clinton administration pulled those proposals back. Subsequent to that, Congress in 1999 passed limitations on our ability to use our inherent reasonableness authority and put a number of requirements in requiring us to come back and look at additional regulatory guidelines before we used it.

We, in fact, as Leslie mentioned, have done a number of demonstration projects for DME that I think have worked reasonably well, and I think the results do hold some promise. We averaged about 20 percent savings in both Florida and Texas, and of those savings, about $1.3 billion we project in our budget savings. It could be lower savings for co-payments and premiums to beneficiaries, as well as the $5 billion in the President's budget over 10 years that we think we would save the program.

I do think you have to be careful when you do this, and I do think there are differences in the way VA operates and the way Medicare operates. When I was at OMB, I had the VA's budget for

4 years. The VA can, in fact, use its market power like a private entity because they usually have 2, 4 percent market power to go out and buy the next piece of equipment on marginal rates, and people are usually willing to sell the extra hospital bed or whatever at a marginally lower rate.

We have to be careful in Medicare in the fact that in many cases we are the market. For some of these supplies, we are 95 percent of the market. So, how we use our market power and how we throw it around, while we are clearly overpaying, we need to be careful. And I think we tried to do this in the demonstrations to make sure that we do not wipe out local small businesses that rely on this and to make sure that when we do competitive bidding, we do it in a way that makes sure we do not use our dominant market power.

However, clearly we need to use this in a much more aggressive way. The demonstration program expires December 31, 2002. We certainly hope it is continued.

The President has proposed competitive bidding in a much broader way in his budget. I believe in the House bill that is likely to come out of the Ways and Means and Commerce Committees in the next 2 weeks, it is pretty clear that durable medical equipment competitive bidding is a major proposal in that. I am happy to hear that you support that, Senator. We would love to work with you and the Senate to get that done. But I think our goal across the board is to find out whether it is durable medical equipment, whether it is other suppliers, whether it is AWP for drugs. The Medicare program has the responsibility to the taxpayers to make sure that we are not overpaying.

PREPARED STATEMENT

On this issue, you have been incredibly aggressive, and we appreciate it. We hope to get a reg out soon, and I do not want to overcommit, but I think in the next month is a reasonable target. It is already out of my Agency and is basically going through the rest of the administration for clearance.

So, thank you very much, Mr. Chairman. I appreciate your having me here today.

[The statement follows:]

PREPARED STATEMENT OF HON. THOMAS A. SCULLY

Chairman Harkin, Senator Specter, distinguished Subcommittee members, thank you for inviting me to discuss the appropriateness of Medicare Part B payments for medical supplies. As you know, at the Centers for Medicare & Medicaid Services (CMS), we have the responsibility of ensuring that some of America's most vulnerable citizens, the elderly and disabled, have access to the health care they need, and that Medicare payment is set at levels appropriate for ensuring that beneficiary access to care is not compromised. At the same time, we must ensure that taxpayer dollars are spent appropriately and safeguard the Medicare Trust Funds from unnecessary waste. Additionally, when Medicare pays appropriately for care, beneficiaries are protected because cost sharing amounts are appropriate as well.

We have a number of potential tools available to help us meet these goals, including the flexibility to adjust payments when statutory payment formulas, based on historic charges, result in payment levels that are either unreasonably high or low. This "inherent reasonableness" authority, which currently is suspended by law, would give us the ability to raise payment levels when they are so low that they threaten to reduce beneficiary access to care; and it allows us to lower payment levels when we are confronted with grossly excessive charges. We also are wrapping up a demonstration project to find better ways to obtain market-based prices for cer-

tain part B items, such as durable medical equipment (DME). The results so far hold some promise. The demonstration has shown to that competitive bidding can produce significant savings for Medicare and beneficiaries. This market-based approach is another tool we are using to ensure Medicare pays appropriately for these items, and we support making competitive bidding for durable medical equipment a permanent part of Medicare.

I appreciate this Subcommittee's longstanding interest in and support of our efforts. I want to thank you, Chairman Harkin, for pushing us to move forward on the inherent reasonableness regulation. It is a priority of mine, and I can assure you we have been working for months to finalize the regulation. The regulation is complicated, and as you know, we have a number of competing regulatory priorities at CMS. Nevertheless, we intend to publish it soon. I also want to thank Inspector General Rehnquist and the GAO for their valuable assistance in helping us to identify areas where we can improve our payment processes. We have worked cooperatively on many issues—and this cooperation can only work to better serve the nation's 40 million Medicare beneficiaries who depend on us.

INHERENT REASONABLENESS AUTHORITY

The Secretary has always had inherent authority to determine what charges are not reasonable; and in the mid-1980's, Congress made explicit this authority to correct "unreasonable" Medicare payment amounts for specific items or services paid for under Medicare Part B, including drugs, laboratory services, and DME. This authority now excludes physician services. The goal is to allow us to ensure our payments are appropriate when statutory formulas call for payment levels that are grossly deficient or excessive. This sort of situation could arise when:

—The marketplace is not competitive, for instance, when a limited number of suppliers furnish the item or service;
—Medicare and Medicaid are the sole or primary sources of payment for a category of items or services;
—The payment amounts for a category of items or services do not reflect changing technology, or changes in acquisition, production, or supplier costs;
—Payment amounts are grossly higher or lower than acquisition or production costs;
—There have been increases in payment amounts for a category of items or services that cannot be explained by inflation or technology;
—The payment amounts in a particular locality are grossly higher or lower than payment amounts in other comparable localities, taking into account the relative costs of furnishing the category of items or services in the different localities; and,
—The payment amounts are grossly higher or lower than the payments made for the same category of items or services by other purchasers in the same locality.

In situations like these, Medicare might not be paying enough for suppliers to continue providing the items or services, and, as a consequence, Medicare may risk forcing them out of the market, leaving Medicare beneficiaries without access to needed care. Conversely, Medicare might be vastly overpaying for an item and we need to ensure that we are managing the taxpayers' money appropriately. So we might determine that Medicare payment levels ought to be raised or lowered. In theory, inherent reasonableness gave us the authority to make common sense changes to payment levels in order to protect beneficiary access, and beneficiary and Trust Fund dollars. Unfortunately, the process for actually using this authority was quite cumbersome, and so the authority has seldom been used successfully.

Because the process was so cumbersome, in the Balanced Budget Act of 1997 (BBA) Congress tried to streamline inherent reasonableness. The BBA simplified the process for making Medicare payment level adjustments of 15 percent or less, up or down, in any year. It also gave Medicare Carriers, the local private sector contractors that process and pay Part B claims, the authority under CMS's supervision to adjust payments based on inherent reasonableness. And it gave CMS some additional authority to streamline the inherent reasonableness process.

In January 1998, CMS, then the Health Care Financing Administration, published an interim final rule implementing the inherent reasonableness provision of the BBA. Later that year, the Agency compared Medicare's payment levels for a number of items with the amounts paid by the Veterans Administration, and we found some disturbing instances where Medicare, and therefore beneficiaries, were paying far too much. So the Agency proposed reducing unreasonable payment levels for:

—Two types of walkers, up to 37 percent;
—Commode chairs, up to 40 percent;

—Two types of transcutaneous electronic nerve stimulators, up to 57 percent; and
—Vacuum erection devices, up to 46 percent.

Likewise, Medicare's Durable Medical Equipment Regional Carriers also found circumstances where they were grossly overpaying for certain products, and they proposed to reduce Medicare's payment for those items, including:

—Glucose test strips, up to 3.38 percent;
—Lancets, up to 35.72 percent;
—Catheters, up to 24.02 percent;
—Enteral products, by 16.39 percent overall;
—Albuterol, by 10.64 percent overall; and
—Eyeglass frames, up to 21.04 percent.

The medical equipment industry expressed strong concerns about these proposed reductions and, consequently, Congress took action to ensure that we were adjusting payment levels appropriately. In the Balanced Budget Refinement Act of 1999 (BBRA), Congress requested that the General Accounting Office (GAO) examine our proposed regulation and the Carriers' use of the inherent reasonableness authority. The BBRA also suspended Medicare's inherent reasonableness authority until the following conditions were met:

—The GAO released its report regarding the interim final regulation and Carriers' use of inherent reasonableness;
—CMS publishes a notice of final rulemaking on inherent reasonableness that responds to the GAO report and to comments received in response to the 1998 interim final regulation;
—CMS issues a final regulation that reevaluates the criteria included in the interim final regulation for identifying payments that are excessive or deficient; and,
—CMS takes appropriate steps to ensure the use of valid and reliable data when exercising inherent reasonableness authority.

I know that you, Mr. Chairman, were disappointed to see CMS's ability to use inherent reasonableness authority restricted. Additionally, I want to note that inherent reasonableness is a two-way street. For every concern we hear that we are overpaying, we receive other comments that we are not paying enough for items like ostomy supplies or catheters. Giving Medicare the flexibility to make common sense changes that protect beneficiaries and the Trust Fund simply is the right thing to do, and the Agency is committed to moving forward in that direction.

The GAO issued its report in July 2000, and was generally supportive of CMS's previous implementation of inherent reasonableness authority. Since then, CMS has been working hard to develop a final rule that addresses all of the GAO's recommendations as well as the numerous comments that we received on our 1998 Interim Final Rule. I agree with you, Mr. Chairman, that inherent reasonableness represents a potentially potent tool for protecting beneficiary access to needed care, reducing beneficiary cost sharing, and safeguarding the Medicare Trust Funds from waste. And to ensure our adjustments are fair to the industry, before we make a payment adjustment we intend to first publish a proposed notice informing affected parties and soliciting comments. We would then respond to the comments received and publish our response in a final notice. Similarly, under CMS supervision, Carriers would notify affected parties within their areas and allow 60 days for comments. The final rule, which would reestablish inherent reasonableness authority, is a priority for me, and I have been doing everything in my power to ensure that it will be published expeditiously, taking into account the important recommendations from GAO and the comments we received on our 1998 interim final rule.

COMPETITIVE BIDDING

While we have worked hard to finalize the inherent reasonableness rule, we are exploring other ways to ensure that we are paying appropriately for items and services. With the authority provided in BBA, we are conducting a demonstration project where private sector businesses competitively bid to supply DME and prosthetics, orthotics, and supplies for Medicare beneficiaries. Although the demonstration and our evaluation of it are still ongoing, the results appear to be promising. When suppliers bid prices in competition with one another, it allows the market price to become the Medicare allowable price. The Administration supports expanding the effective use of competition to save money and improve the quality of DME services for Medicare beneficiaries. This is one element of the President's proposals to modernize the Medicare program by using market forces to help us avoid setting prices that do not respond to improvements and efficiency and obtain savings for the program and its beneficiaries. As long as the federal government does not allow any one company to obtain an overly dominant market share for a particular product,

competitive bidding can replace inflexible fee schedules set by law and can be a fair, effective way to ensure that Medicare pays competitive, fair market prices for DME.

The demonstration currently is ongoing in Polk County, FL, and San Antonio, TX. In these two areas we requested bids for:

—Oxygen;
—Hospital beds;
—Surgical dressings;
—Urological supplies;
—Enteral nutrition;
—Manual wheelchairs;
—Nebulizer drugs; and,
—Simple orthotics.

To date, we have been successful in reducing Medicare costs for most of these supplies. Savings vary by site and product, but averaged 20 percent in the latest bids in both Florida and Texas. This saves money for our beneficiaries, by way of their cost sharing, and the Medicare Trust Fund. It will save around $5 billion over ten years, of which nearly $1.3 billion is through lower premiums for beneficiaries, by paying more appropriately for medical equipment.

Moreover, one of our fundamental goals in the demonstration is to maintain high quality service for our beneficiaries. For example, we chose multiple suppliers in each category, so competition gives suppliers an incentive to provide high quality products and services. We also developed specific quality standards for the demonstration that the suppliers must meet. Moreover, winners of the bidding competition must pass site inspections and reviews by an expert panel before they can supply items and services to our beneficiaries. Additionally, we hired an ombudsman for each site to solve any beneficiary difficulties, including quality concerns.

We also have paid close attention to the providers in this project. A large part of the DME industry is made up of small businesses, and we were very careful to ensure that small businesses could compete for the Medicare DME business on a level playing field with the large suppliers. For instance, by choosing multiple winners for each product category, we were able to choose many small suppliers rather than only the largest suppliers. Additionally, for our San Antonio demonstration, the suppliers were not required to serve the entire area, but could choose to bid for just one county, giving small businesses an even better opportunity compete. As a result, more than three-fourths of the suppliers we selected are small businesses.

This demonstration will end on December 31, 2002, according to the authorizing legislation. The President has asked Congress to make competitive bidding a permanent part of Medicare, and it appears likely to be included in the draft bill emerging in the U.S. House of Representatives. By encouraging suppliers of durable medical equipment to compete on quality and price, and by making sure that beneficiaries have choices about how to get their equipment, we can both save money and improve the DME services that beneficiaries receive. Like inherent reasonableness, it makes sense for beneficiaries and taxpayers—it is the right thing to do. I look forward to working with this Subcommittee and your colleagues in Congress enact legislation this year to ensure that we continue and improve upon this important initiative.

CONCLUSION

We know that Medicare, in some instances, pays much more for equipment and services than other health care purchasers. Additionally, sometimes we may not pay enough. Although this payment disparity often can be attributed to Medicare payment formulas required by law, it is nonetheless an important concern and we are working hard to address it. The competitive bidding demonstration embraces market forces to ensure Medicare pays a fair price for the items and services it covers, and by all accounts an effective competitive bidding program may achieve more appropriate Medicare payments for DME. Likewise, our inherent reasonableness authority gives us common sense flexibility to correct grossly excessive or inadequate payment levels when statutory payment formulas produce them. We are in the last stages of finalizing our inherent reasonableness regulation, and we hope to publish it soon. Thank you again for inviting me to be a part of this discussion today, as well as for your continuing support for Medicare, and your commitment to protecting beneficiaries and the Trust Fund. I am happy to answer any questions.

INHERENT REASONABLENESS AUTHORITY SUSPENSION

Senator HARKIN. Thank you, Mr. Scully. I thank you for your paying attention to this and being aggressive on this issue. I would

like to explore with each of you where we are, where we have been and what the situation is right now.

Mr. Scully, in your written statement—and it may have been just a mistake in writing or something—in your first page, you say, "This inherent reasonableness authority, which currently is suspended by law."

Mr. SCULLY. I was afraid you would notice that, Mr. Chairman. I saw that on the way over this morning.

Senator HARKIN. Okay, it was a misprint. All right, thank you.

Mr. SCULLY. You are right. It is suspended by law because of us. As soon as we put out our regulation, it is no longer suspended by law, and you are correct. The thing holding it up is us, and we hope to remedy that soon.

Senator HARKIN. When the GAO issued its report in July 2000 under the law that was passed—it has been nearly 2 years—some on your watch, some not on your watch—you could have issued regulations on this. Having been at this for 12 years now, I keep hearing, well, something is going to happen, something is going to happen, and something is going to happen.

Now, I went through that whole process in the 1990's when Senator Specter was Chair here, and I can tell you exactly what happened. We passed it here, and then it was changed in the conference with the House. Then we came back again with the competitive bidding which we passed here. The Senate passed it. Then it went into the House and again was put into a demonstration. Then we had the two demonstrations. Then we had the study that had to be done by GAO before you could go ahead with inherent reasonableness. But it was said that as soon as the GAO report was filed, then you automatically could use the inherent reasonableness clause again.

So, we have been waiting for these regulations. You just mentioned next month. Can we pretty much count on that?

Mr. SCULLY. Well, I apologize if there was a holdup on my part. I have been on the job exactly 1 year last week, and I think, to be honest, the first time this came up with me as an issue—as you know, Nancy Ann had spent some time on it, and there was a gap between administrations, obviously, where there was not a political appointee running the agency.

The first time it came up to me probably was last, I think, October from Tom Hoyer, who I think both these agencies know basically is the person who has done home health and DME for years in the agency. As soon as they brought it up and said, should we do an inherent reasonableness regulation, I said yes. I think we have pretty aggressively pushed forward since then.

It has been out of CMS for not that long, but the fact is it has to go through the administration for clearance and OMB. And the Small Business Administration, appropriately, has had a lot of concerns over the years because a lot of these providers are small businesses, and I think we're hopeful. Your interest certainly helps, but CMS clearly would like to do this. I believe the Secretary would like to do it, but your strong interest certainly helps.

But there is a lot of concern in the equipment business. There is a lot of concern from small providers. A lot of them are small

businesses. We certainly want to make sure we take the right safeguards to protect small business. But it is a controversial issue.

Senator HARKIN. But give me a date on that. Give me a timetable on the regulations.

Mr. SCULLY. Well, to some degree, Mr. Chairman, to be honest, it is out of my control once I send it into the administration process. I certainly hope it is going to be done—I would like to have it done certainly if not before the July 4 recess, certainly right after that.

Senator HARKIN. The regulations are out of your shop.

Mr. SCULLY. It has been out of my shop for a while. I hope to have it through the Department and the administration within a month. I think that is certainly a reasonable goal.

COMPETITIVE BIDDING

Senator HARKIN. I also wanted to ask about competitive bidding. That is in the President's proposal and I am hopeful that we can move ahead very aggressively on that. Can you see working together with the Congress, if there is some Medicare bill that goes through this year, of starting that process this year, building on the two projects that we had in Texas and Florida?

I do have a question for Ms. Aronovitz, which I am going to follow up on, in terms of making this nationwide. You said there may be some problems with that.

Would it be the administration's intention to move ahead on this, since it was in the President's proposed 10-year budget plan, this year?

Mr. SCULLY. Absolutely, and we have been encouraging the Ways and Means Committee and the Commerce Committee in the House and the Finance Committee over here to put it in their bills. We think it is a good proposal. I will say that everybody is looking for savings, for offsets this time of year.

My major concern, having been a formerly bad antitrust lawyer, is that the Government needs to use its market power just like private payers do, and I think we need to be careful—in many cases, we are 95 percent of the market—that we do this in a reasonable, balanced way and that we make sure that we do not—you know, we do have a much different market leverage than the VA does or even some of the other Government programs.

So, I clearly think this is the right way to go. I hope we do it in a sound, reasonable, and balanced way so that we do not set expectations too high so that we have to be too aggressive because I think this program has great potential. But I hope it does not blow up the first time we try it.

Senator HARKIN. Well, we just had these demonstrations.

You mentioned the impact on small business. This has come up repeatedly time and time again over the last 12 years. But it has been my understanding—and maybe you can talk about this or Ms. Aronovitz—that in the two demonstrations, that in Texas a significant number of the winning bidders were small businesses. Is that true?

Mr. SCULLY. 77 percent, I think, were small businesses, and we made a big effort. I think 16 of the 40 bidders actually got a contract. But I think that is the kind of thing that you do to make

sure—when the Government comes in and has 95 percent market power, whoever does not get a bid is out of business. So, I just think we need to make sure we are conscious of that.

Senator HARKIN. What is the thrust of what you just said?

Mr. SCULLY. I think we have done it appropriately in San Antonio and I think we have done it appropriately in Polk County in Florida.

Senator HARKIN. But obviously, if some people are losers on the bid, they do not get it.

Mr. SCULLY. Sure. Well, they may get it in another county. And I think that is the nature of competitive bidding.

I think the way we have done our demonstrations is exactly fine. I just think we need to focus on—some of the proposals I have seen in Congress—I guess my concern is the budget assumptions. If they get too high on how much we are going to save from this, it will drive policy that limits our ability to protect the small business interests.

So, I am certain we can do it. I think the demonstrations are well balanced, and if we do it based on those demonstrations, I think we will be fine. I also think there are some places like in Iowa and in rural areas that we have to be more sensitive and probably may not be able to do competitive bidding.

Senator HARKIN. What have we learned about rural areas from these two sites, Texas and Florida? Did we learn anything about it? Were there some rural areas involved?

Mr. SCULLY. No. They are basically urban. Polk County in Florida is mostly urban, and San Antonio, Texas obviously is urban. So, I think there may be some different challenges in rural areas. I think clearly if you are trying to provide motorized wheelchairs, for instance, in a rural area of Iowa, there may only be one person doing it. So, having a competitive bid—it can probably well be done, but I think you just have to be a little bit more cautious.

Senator HARKIN. Although even in rural areas, there are urban places close by where they have this, whether it is Des Moines or Omaha or the Quad Cities or someplace where you will find plenty of interest in this.

Mr. SCULLY. Well, even there I think some combination of inherent reasonableness where clearly there is one provider where you can go in and say we are overpaying and lower the prices, that combined in markets where maybe there were not multiple bidders, certainly we can look at the prices and lower them. We are clearly overpaying in a lot of cases.

Senator HARKIN. It is my assumption and what we have intended all along is if we have competitive bidding, we do not do away with inherent reasonableness. Let me see if I can explain how I envision it.

In the past it has been those who are selling these items start at the top level. They get the highest prices. CMS could use its inherent reasonableness to try to get it down. What I envision is competitive bidding where the Government and the beneficiaries get the best price. If there are reasons why it needs to be higher than that for a rural area or for whatever reason, then you can use inherent reasonableness to get the price up. That is the difference. I think the taxpayers and the beneficiaries will get a better deal

if you use your inherent reasonableness to answer those few cases where, for whatever particular reason it might be, that a competitive bid simply won't work and we have to have a different device. That is how I envision it working, and if you have any comments, that would be fine.

Mr. SCULLY. No. I agree totally.

Senator HARKIN. Ms. Aronovitz, I did have a question. But I have been taking enough time here, but I would yield to Senator Murray from Washington both for an opening statement and for any questions you might have. Then I will pick it up after you.

OPENING STATEMENT OF SENATOR PATTY MURRAY

Senator MURRAY. Great. Well, thank you very much, Mr. Chairman. First of all, let me thank you for having this really important hearing that you are having today. Washington State has 750,000 seniors and disabled who rely on Medicare, and there are a lot of problems within the Medicare program that need to be addressed and one of them really is making sure that Medicare payments for medical supplies are adequate and accurate. So, I appreciate your statement today and our witnesses who are here today to talk about this issue.

I am going to take the advantage of the fact that Mr. Scully is here to bring to his attention an issue that I think is critical regarding Medicare because I am concerned about any issue that prevents those on Medicare from getting the care they need. That is why I am especially troubled by one of the underlying issues that is limiting access to seniors and disabled in my State.

The recent 5.4 percent reduction in physician payments, the deep reductions imposed by CMS as a result of the Balanced Budget Act have really created major problems in my home State of Washington. These cuts have been forced on providers who are already in my State receiving less than adequate reimbursement rates and payments from Medicare. Because of a flawed, outdated formula, health care providers in my State of Washington receive significantly less reimbursements than providers in other States for providing the same service. My State ranks 42nd in the Nation for beneficiary payment.

I know the chairman is 50th on that list, the lowest in reimbursement. I know he shares my passion on this issue and I really want to bring this issue to this committee's attention, to Mr. Scully's attention to try to recognize how critical it is.

The results of these less payments are really devastating on seniors and the disabled in my State. We have providers that are refusing to take new Medicare beneficiaries. We have doctors who are leaving our State and hospitals that are operating at less than 2 percent margins. Hospitals in my home State are competing for a shrinking pool of nurses, as we all are, and health care professionals nationwide. When the reimbursement levels are less in our State, they go to where they are much higher. And I love Florida and California, but I do not want all the doctors and nurses and health care professionals in my State moving to those States because they can get better reimbursement, but that is what is happening.

Again, I know Chairman Harkin is well aware of this and is working with me as we try to address this.

But, Mr. Scully, I wanted to bring this up with you because you were out in my State recently. And I appreciate your coming out there, but I was, frankly, fairly surprised at some of your comments that I read in the press. I was not there, so I am assuming they are accurate, but you can change them if you want. But the East Side Journal quoted you as saying: "I don't think it's a significant problem for seniors," and you said that you believed that doctors were not fleeing, despite legitimate concerns.

I have to tell you seniors in my State were really outraged by those comments. I had a doctor from Olympia who wrote to me after that and said: "Unfortunately, when Tom Scully was recently in our State, he denied the reality of access problems. His agency will never fix this problem until seniors, physicians, and leaders like those in our own congressional delegation hammer home the message that the system is broken and we need to demand a fix."

Mr. Chairman, I am here to hammer home the message. It is broken. It is a problem. It is impacting access.

I have to say I was also very concerned because you were quoted as saying: "The answer is not to give Seattle more, but to give the rest of the country less." Well, first of all, this is not just a Seattle problem. Every rural community in my State is affected by this. But the reality is that giving the rest of the country less is not a solution to this.

I recognize we have a flawed formula, but I think denying there is a problem is not going to allow us to get to a solution. To say that our providers are not being paid too little, but others are being paid too much, just really offers very little hope this is going to be addressed.

So, Mr. Chairman, I apologize for bringing this issue up when your hearing is on another very critical issue, but I wanted to take advantage of Mr. Scully's first opportunity to come before our committee this year to bring this up and to really press you and to see if you recognize that this is an access to health care problem issue in my State that we have to work together to address.

Mr. SCULLY. Senator, I do. I seem to have a rare talent to both be misquoted and outrage people at the same time.

There are a number of questions. I clearly think we have an access problem. By the way, the comment I made about Seattle, which was a misquote, more rather than less, I was complimenting—I was in Iowa for 2 days last week as well, as the chairman knows. What I said basically was that Louisiana—I think the national average per senior in spending is about $7,700 per senior. I believe in Washington State it is about $6,000.

Senator MURRAY. Less than.

COMPETITIVE BIDDING

Mr. SCULLY. Some of the numbers from the State were a little lower because they are a couple of years old. I think this year it is about $6,000. In Louisiana, for instance, it is more like $9,000. In the District of Columbia, I think it is $10,500.

What I was saying was I was complimenting, because I used to work in the Washington State delegation, as you may know, that

there is a good health care culture in Puget Sound and in the Seattle area, and that certainly there are inequities in the system, but to some degree we ought to get some of the other States to operate more like Iowa and Washington State. That way we would not necessarily bring everybody up to $10,500 a year, but to encourage the inefficient States to be more efficient. I was not saying in Seattle, everybody should come down to where Washington State was.

What I was trying to say was that there are some models in Iowa, which happens to have an extremely good health care culture as well, and a lot of this is utilization per patient. And Puget Sound and Washington State does too, and it is inequitable, but to some degree the health care traditions and practices of both Iowa and Washington State are great and should be a model for other parts of the country. So, some of it is redistributing the money more fairly. Some of it is trying to get the health care and medical practices in some of these lower cost areas distributed around the country.

In that case I believe I was misquoted. It was a long town hall meeting, about 3 hours, and we had a pretty lengthy discussion of that. I was not trying to claim that everybody should go down to $6,000 per year. I was saying that some of it is inequitable historical distribution and some of it is that the culture of health care in Seattle, in particular, and Puget Sound, but in the whole State is very positive, and the utilization in Iowa, for instance, has always been much lower than the rest of the country. Iowa, I believe, has the oldest population, close to Pennsylvania, as far as the highest percentage of seniors in the country as well. So, I think that was a little misquote.

On the access issue, I spent a lot of time with physicians, a number in my family. The negative 5.4 percent cut we said repeatedly has to be fixed. The administration supported a fix. I believe again the House bill will at least fix it for 3 years. There is no question the formula is broken.

I have also said repeatedly the RBRVS formula, which I was one of the two people—I think one of my first jobs in the first Bush administration in 1989 was pushing that through.

I believe if you look at nursing home payments, which have been a roller coaster for years, hospital payments, which have been a roller coaster, home health, most of the Medicare payment formulas have been very inconsistent. The RBRVS system has worked exceptionally well since 1989, and I think it is a good system.

It is broken largely because my agency made a mistake, which a lot of physicians do not understand. The physician payment growth—I might be slightly off on the numbers—in the year 2000 was supposed to be under the targets in the law, about 6 percent, and in 2001, it was supposed to be 6 percent as well.

We added a bunch of new codes. There are about 6,500 physician codes. We added a number of new codes in 2000 and 2001, and believe it or not, we forgot to count them. So, we overpaid in bulk. We pay about $66 billion a year out for physician services and physician related services. And by accident in those 2 years, we overpaid by about $3.7 billion one year and $2.5 billion the next year. So, in bulk, under the formula—and it is a very rigid formula—we

overpaid 2 years in a row without knowing it by $6 billion and the law, which is inflexible, recaptures that.

I think the law is broken. I think the fundamental formula for physicians is fair and works and has been by far the most stable payment system in Medicare for the last 14 years. It is broken. It needs to be fixed, and it is not fair. And trying to explain to physicians that they were overpaid in bulk for a couple of years does not go very well. But I do think it is important to explain to them what happened. There was a mistake.

I think the fundamental RBRVS system is solid and works well. I think it has a major glitch in it. The system has a short-term flaw and it needs to be fixed and the administration supports fixing it this year. I certainly hope—and everybody I have talked to in the House and Senate, Senator Baucus and Senator Grassley and others have supported fixing it this year. So, we strongly support doing something to fix it before it goes out.

On the issue of access, many doctors are outraged, as they should be. It is a negative 5.7 percent reduction in their base conversion factor fee this year. If it is not fixed, it is a negative 4.4 percent next year. I do think, and I have said repeatedly, if we do not fix it, we are going to have an access problem. It is inevitable. Doctors are angry. They read a lot of things in their journals and AMA reports about how their fees are getting cut, so they are angry and they are saying they are not taking new Medicare patients. So far, we have not seen, as a matter of access, a major drop-off in access.

ACCESS PROBLEMS

Senator MURRAY. Well, let me just interrupt you. In my State we do have doctors who are now refusing to treat Medicare patients. We have numbers of them. I am happy to get you the statistics on this. This is not a "if we don't fix it, it will happen." It is a "happening right now" issue.

Mr. SCULLY. Senator, I agree. I spent 2½ hours in Seattle meeting with the Washington State Medical Association and I am very sensitive to the issue. I think there is clearly a problem. We still have about 90 percent of physicians taking mandatory assignment, and there is an issue of them taking new Medicare patients. And it probably has been more acute and I have heard more about it in Puget Sound than some other areas.

But I spent a lot of time also with patient groups and AARP and others, and I think if we do not fix it, we are going to have an enormous problem. As of right now, I think a lot of it is angry physicians, and they have a right to be angry. But I think we have not yet seen from the AARP or other patient groups a major systemic access problem.

Senator MURRAY. Well, I will just tell you it is an access problem in my State. I want to work with you on this. I will work with the chairman. I will work with anybody else, but I am going to keep talking about this.

I will just end with a story, Mr. Chairman. I was up in Sequim, Washington. It is about 3 hours from Seattle in the northwest section, a small, retired community, probably the highest number of seniors. And they are livid because a number of doctors are refusing to take Medicare patients. A woman came up to me in a park-

ing lot with a cast on her arm, told me she had broken her arm about a month before that. The doctor put a cast on it. She went back and he is now not taking Medicare patients, and she wanted to know how she was supposed to get the cast off. This is an access problem.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Murray. I appreciate your bringing this up because it is a big issue in Iowa too. Well, it is a big issue in a lot of States where they are way below the national average. Some States are way above it. We have seniors in our State that many times will go down to Texas or places like that for the winter, and they come back and they say, Medicare down there, you can get eye glasses. You can get all kinds of things, but you cannot get them in Iowa. And they pay the same amount per month there as they do in Iowa. So, it really is a fairness issue.

But we could go on with that for some time here. I wanted to bring it back to the focus on this issue. As Senator Murray said, it is a big issue. It is one that cannot be put off any longer. We have got to make some changes this year in that reimbursement formula.

I also believe that we cannot afford to wait any longer on this issue either, about cutting down on some of the waste, fraud, and abuse. I guess those are the words that are used, but just the wasteful payments that are being made in Medicare. We know they are going out, and we are close to getting our hands on this.

Ms. Aronovitz, I wanted to ask you about the part of your statement wherein you said that the positive results achieved from the two competitive demonstrations may be difficult to expand on a national scale. This is due to the need for a labor intensive outreach effort in each community and an ongoing monitoring of beneficiary access and product quality. Some of that I think I understand. Some of it I do not understand. Could you elaborate on that please?

Ms. ARONOVITZ. Yes. I would also like to address Senator Murray's comment for a moment. Although she apologized for getting off the topic, I think her comments related directly to the topic. What Senator Murray is referring to is the fundamental question of how CMS knows what it is paying for and whether the Agency can defend what it is paying for.

There were a lot of changes in the BBA of 1997 that affected many different industry groups. CMS will always have to deal with industry groups and others who are upset or concerned about any changes in price.

We think that with DME or with any other payment system, CMS has to have the information technology infrastructure to collect data so that the Agency can defend its prices and knows internally what the correct price should be. Some of the previous BBA give-backs to providers have occurred because CMS could not explain beneficiary access issues or outcomes issues, and it could not defend its decisions to move in a certain direction.

This is another situation where, with better information, we could probably know exactly how much higher the physician fee schedule rates should be. Clearly it is a legal formula, so it does not allow a lot of flexibility, but obviously, CMS needs to have

much better information about what it is paying for and how much it should be paying. I just want to make that clear.

We think that the early success in competitive bidding shows that it could be a very important tool for CMS. Unfortunately, we do not think it is the complete answer and it is clear that you agree with that.

Senator HARKIN. I just want to interrupt you right there. Since we started on this years ago, the GAO has repeatedly testified before this subcommittee in support of giving Medicare competitive bidding authority and that is still your position.

Ms. ARONOVITZ. Absolutely. That is 100 percent correct.

Senator HARKIN. I did not want to misinterpret that.

Ms. ARONOVITZ. You did not misinterpret it. Not only do we think it is important to have CMS use competitive bidding authority in these types of demonstrations, but we have also talked more broadly about giving CMS wider contracting authority in other aspects of its operations.

In terms of competitive bidding, there are some important lessons that CMS and we are learning about how implementation should occur. One of the early and important issues that made these bidding demonstrations successful is the fact that there was an on-site ombudsman who could understand the environment and could settle issues that arose. You need to have ongoing monitoring to ensure that providers receive a fair price and will be able to stay in the market, and that beneficiaries have access to the items.

Also, there is a lot of outreach and education that must occur in order to help the community understand what the changes will be. Therefore, there are costs associated with making a demonstration effective, and we want to be certain that you understand and accept the fact there is a lot of hard work, money, and resources required to make these successful. This fact needs to be considered as the demonstrations are expanded.

COMPETITIVE BIDDING

Senator HARKIN. In reading through the testimonies last night, I made a note on my paper on this, and then Senator Specter brought it up too. Why do you not just buy from the VA? Mr. Scully or Ms. Aronovitz.

Mr. SCULLY. Well, I think the issue there is really market clout, the same issue with drugs.

Senator HARKIN. It is what?

Mr. SCULLY. Is market power.

Senator HARKIN. No. I am just saying why does Medicare not just say, okay, VA, you are now our purchasing authority. You buy all these things. We are going to buy them from you at cost. Obviously, VA is not in the business of making a profit.

Mr. SCULLY. Well, the VA would probably hate that for one reason. They would end up paying higher prices. We went through the same thing on Medicaid. Medicaid drug rebates, for instance, which I was involved——

Senator HARKIN. Why would VA hate it?

Mr. SCULLY. Well, I will give you just one example, Medicaid drug rebates, which were passed in 1990, which I was involved in again in the first Bush administration, where the States went out

and got roughly—the drug prices are a moving target, but roughly 15 percent discounts off of whatever market prices theoretically were. VA was getting a lot less than that. We had to exclude VA. The subcommittee, in fact, went out—actually it was the HUD, VA subcommittee. They excluded VA from that because VA was getting lower prices. If VA became the best price in the Federal Government, the drug companies were not willing to sell it to everybody for what—you know, VA was able to go out and use their 4 or 5 percent market clout to get really lower prices. Once that became the best price, their price was going to go up.

For example, let us say with 4 percent market clout, you can go out and get tremendous discounts because somebody is willing to sell you the next marginal commode chair or whatever else for the lowest possible price. Once the Government is buying every commode chair at that price, they are not going to give the VA that good a price. The price is going to go up. Once you throw Medicare in there, Medicare plus VA is the entire market.

Senator HARKIN. Let me interrupt you. VA goes out with competitive bids.

Mr. SCULLY. VA gets competitive bids for 4 percent. I am just saying hypothetically, if you went out and said that a commode chair—I cannot remember the price—but let us say that we are paying $200 and maybe the VA is paying $110.

Senator HARKIN. Let us see. What was it? VA is paying $32 and Medicare is paying $109.

Mr. SCULLY. Okay. Let us say that the commode chair—I am not an expert, thank God, in commode chairs. If you are a commode chair manufacturer and you are making the commode chairs and your actual cost is $30, you are probably willing to sell them to the VA in bulk for $32, but you are probably not willing to sell them to the entire Government for $32. $100 and some is probably way overpriced, but if you went out and said VA and Medicare together are going to go out and competitively bid for commode chairs, you are probably not going to get that price.

Senator HARKIN. You know, I do not understand that, Mr. Scully. There are always cost reductions in mass manufacturing. So, obviously, if a company is making commode chairs and they can make a profit of $2 each for selling 100 chairs, they could make a lot more profit selling 1,000 chairs because the cost of production will come down as they mass produce it seems to me.

Mr. SCULLY. Well, I will give you the example from the hospital business. This is the same issue when you get into centers of excellence in hospitals. Let us say Medicare went out and said we wanted to have competitive bidding for hip replacements in northern Virginia. We do all the hip replacements. Probably 90 percent of the hip replacements are Medicare. So, if you went out and did that, an insurance company could come along and get a lower price if they have 2 percent market share because a hospital—let us say you are at Alexandria Hospital and an HMO comes to you with 2 or 3 percent market share. You may get a significant discount. If a hip replacement costs $10,000, they may be willing to tell Blue Cross of Northern Virginia, we will give you one for $8,000 because we are already doing a lot, and on the next marginal hip replace-

ment to fill an empty bed, we will do for a little less. But you cannot do every one of them for $8,000.

That's exactly the problem, for instance, with centers of excellence that I have with that for Medicare. If we went out with Medicare and said we want to take competitive bids for hip replacements in northern Virginia, INOVA, who is the dominant player out there, would do the lowest bidder. Everybody else would have to get out of the hip replacement business and there would not be any competition left, and they would marginally raise their prices over the future years.

Senator HARKIN. But you could go out of State for that. Why would you just limit it to northern Virginia for the bids?

Mr. SCULLY. Well, most patients, unfortunately, on Medicare want to go to a local facility, a local hospital.

Senator HARKIN. You are talking about the procedure.

Mr. SCULLY. Yes, procedure.

Senator HARKIN. We are not talking about competitive bids for procedures, are we?

Mr. SCULLY. I am just using that as an example.

Senator HARKIN. I thought you were talking just about the replaced hip.

Mr. SCULLY. Let us say motorized wheelchairs.

Senator HARKIN. We are not talking about procedures, Mr. Scully. We are talking about equipment and supplies, medicine, that type of thing.

Mr. SCULLY. I agree. But let us say hypothetically that we went out—if the Veterans Hospital up on North Capitol Street went out and did competitive bidding for wheelchairs, they would probably get the wheelchair suppliers to sell at their lowest marginal cost because they are making the wheelchairs anyway and they will sell it for the lowest marginal cost. If Medicare went out and tracked onto the VA's price list, we would have combined 95 percent of the mobilized wheelchair markets and the entire cost for the entire sector would go up because they are not going to sell them all for that lowest marginal price. I think that is just pure economics.

Senator HARKIN. I do not understand. That flies in the face of WalMart's success.

Mr. SCULLY. We have far more market clout than WalMart does in the Medicare program. As a percentage of buying these devices, in some cases we are the entire market. WalMart never has more than, say, probably 10, 12 percent market share.

Senator HARKIN. Well, it has been my experience in my lifetime, Mr. Scully, that if you had that much clout in the marketplace, as demand goes up—and that is what we are talking about. This is more demand from one buyer—that if the seller is increasing the prices exorbitantly, you will find other sellers come in. You will find other people saying, wait a minute. I can make that cheaper than that.

Mr. SCULLY. It is basically an antitrust issue and I believe the Government needs to operate just like a private company does in antitrust. Let us say hypothetically we went out and did wheelchair bids, competitive bidding nationally. My guess is the biggest mobile wheelchair maker, which is probably Invacare, would come in, give us the lowest price. They would run everybody else out of

the business. We would have one big supplier left over the years and then they would jack their prices back up. It is just a pure antitrust model. It is the same issue that Microsoft has. I mean, we have so much market clout. I totally agree with you we need to use it, but we just need to use it in a way that we do not blow up the market because the VA is a relatively small purchaser, both on drugs, wheelchairs, devices. They have 2, 3, 4 percent market clout. Medicaid, generally in most States, has 12, 13 percent. Medicare in some of these devices has 85, 90 percent. We are the market. And if we went out and just found one——

Senator HARKIN. But we just found, Mr. Scully, in the GAO study that I believe—correct me if I am wrong—in I do not know how many instances Medicaid is paying less than Medicare.

Mr. SCULLY. In some instances, but the Medicaid prices are much closer to Medicare, and Medicaid has some of the same issues, which is their bigger purchasing power. But still Medicaid in most places has probably a third the clout of Medicare. I think actually in their testimony GAO, in probably a more cogent way, made exactly this argument. They basically made this argument in their testimony.

Ms. ARONOVITZ. Maybe I could shed some light on this. We definitely think that CMS needs to use current prices. The Federal Supply Schedule, which is the VA schedule of prices, is a great index to use.

We do say, however, that to assure access for beneficiaries across the country and to be certain that providers get a fair price and remain in the market, there would need to be some markup from the VA Federal Supply Schedule. A lot of it depends on the relationship between the beneficiary and his or her provider. The provider who delivers the wheelchair, who maintains it, who fixes it if it breaks—this provider has a relationship with the beneficiary. If a Medicare beneficiary takes a nebulizer drug and something happens which requires the nebulizer machine to be repaired, there can be service costs associated with some DME.

We think that CMS is currently paying prices that are much too high. Some prices are higher than market prices. We think that if CMS used the Federal Supply Schedule prices and could build from those, it could save a tremendous amount of money. It would be paying somewhere in between——

Senator HARKIN. Why can they not know that?

Mr. SCULLY. I think we agree on that. I think if you look at the savings, for instance——

Senator HARKIN. My question is—you said they do not know. Why can they not know it?

Mr. SCULLY. In fact, the original regulation that HCFA came out with in 1998 was largely based—and I think that was so controversial—on a hybrid of the VA supply schedule. So, I think we can look at that.

I think in the GAO testimony, they point out that the savings versus—or maybe it was the IG's. Excuse me. The savings that they said versus VA was $958 million versus Medicaid was $193 million and versus FEHBP was $118 million. I think the reality is we probably cannot save as much as VA. We are probably somewhere between what FEHBP and VA is, and I think that is where

our estimates and our competitive bidding demo show probably somewhere around $300 million or $400 million a year.

I think we clearly can save a lot of money. I just do not want to raise the bar so high that we just are not in the same situation as VA, and I am not sure we can ever get the same exact discounts VA——

Senator HARKIN. Just a second, Mr. Scully. I want to understand if I heard you correctly. We are talking about 16 items that the Inspector General's Office looked at, and if you use the median VA price compared to what Medicare is paying for those 16 items, the potential savings per year, $958 million. Then you pointed out that using Medicaid, which was $193 million, and you said you probably would fall somewhere in between there, $200 million or $300 million a year. I saw Ms. Aronovitz nodding at that.

I am saying to myself, wait a minute. We are talking about 16 items, Ms. Aronovitz and Mr. Scully. And as I look at these, walkers, commode chairs, pressure pads, nebulizers, TENS units, and all of the things we talked about here, I find it hard to believe that you cannot get the same price for these items as VA. I am talking about just these items. Now, there may be some others, I will grant you, that are highly technical, that are different where Medicare may have to pay different than VA. But I am talking about just these 16 items. You are telling me you cannot get an IV pole savings for the same thing or a standard wheelchair? I mean, these are standard items. When you look at these, I just find it hard to believe that on those 16 items that CMS cannot get the same price as the VA and maybe even better.

Mr. SCULLY. Well, Senator, the easy thing for me to do would be to agree with you.

Senator HARKIN. I understand what you are saying is that in some cases you may not be able to get the same savings as VA. I understand that. I am just talking about these 16 items.

Mr. SCULLY. Well, I will just try to pick out one of these 16. For example, just say the hospital beds. The median Medicare price—I am just looking at the IG's list—we are paying $1,754.55. VA is paying $762. If you look over to the FEHBP, they are paying $1,397. Clearly we are paying way too much, but the VA can go to all the bed manufacturers, pick one with their 3 or 4 percent market share and say we want the lowest bid. Well, they are already making beds anyway. This may be very close to their costs, and they may be selling them for absolute cost to the VA. We are not going to be able to get that from a broad range of suppliers. The VA probably picks one nationally and buys all their beds from them. So, I just do not want to raise expectations to think that Medicare—we could go out and say we are going to buy all hospital beds for Medicare from one supplier. We would wipe out all the rest of them.

Senator HARKIN. Now, first of all, Mr. Scully, I will take issue with you there. I will lay you 10 to 1 odds—more than that—that whoever is selling that bed for $762.10 is not selling it at cost. They are making money on it. They are not going to sell it at cost. They are making money on it.

I will buttress that by pointing out that when Congress enacted a 30 percent cut on oxygen, I heard the same story about, oh, it

is going to put people of business. Then we went out for competitive bids and we got people actually bidding lower than that. And they are not losing money.

Mr. SCULLY. I agree. Oxygen is a good example. In fact, the report you are going to see us come out with next week on home health is going to——

Senator HARKIN. So, I am just saying I heard this story before that, oh, gosh, it is going to be very bad. But even when we cut it 30 percent, competitive bidders came in and bid actually—I forget—16 percent below that and they are making money.

Mr. SCULLY. And I hope that is the case. I think in fact when you look at our competitive bidding——

Senator HARKIN. We ought to get the IG's Office a little bit more involved here. I would like to know how many bed manufacturers are there out there that would make a bed like that, a hospital bed, semi-electric, head and foot adjustments. That is the typical hospital that I see when you go in and you punch the button and they go up and down. How many manufacturers are there out there? I do not know. Are there more than enough and what is the cost of manufacturing one of those? I have no idea.

Ms. REHNQUIST. Well, I certainly do not know, Senator, but one distinction on a bed, it seems to me, is that Medicare is not simply a supplier. It is an insurer, so it is reimbursing a DME company to provide the bed to a beneficiary and to service that bed, at least up until now—and that brings up the whole capped rental category too—and provide repairs to that bed. VA would never do that. VA is simply a purchaser and a supplier.

Mr. SCULLY. VA is generally buying beds for hospitals and nursing homes. In this case, it is usually us buying it at home to be delivered at home, serviced at home.

Ms. REHNQUIST. Exactly. The same thing I know would apply to oxygen where they have to come out monthly and service the equipment, and take the oximetry test to see if it is the right level of oxygen.

Mr. SCULLY. Mr. Chairman, I think you are pushing us exactly in the right direction. I am totally supportive. I am just trying to make sure that expectations where we can save are reasonable, so when I come back in a year and talk about it, we are——

Senator HARKIN. Well, that is true.

Ms. ARONOVITZ. Yes, I think that Medicare could use its purchasing leverage by developing reasonable and defensible prices. Right now, a lot of Medicare's payment rates are not reasonable or defensible. If prices are reasonable and defensible, they could be pushed lower in order to maintain the competition needed in order to continue to sustain low prices. We are trying to explain that this is important for Medicare.

Senator HARKIN. I understand that. I would still like to get a better handle on the costs of these items and what the markup is. I mentioned that saline solution, for example. That has got to be a huge markup. That is just unreasonable. But that is just one item.

Ms. Rehnquist, I think it was in your testimony. We were talking about the——

Mr. SCULLY. Mr. Chairman, can I ask you a question just because I appreciate your intense interest in this?

Senator HARKIN. Yes.

MEDICARE DRUG PRICES

Mr. SCULLY. There is a very parallel interest, which is in the GAO testimony, on average wholesale prices for drugs, which, if you got into it, would probably shock you 100 times more. So, I hope we can get you just as interested in that issue because what we are paying for on Medicare drug prices for outpatient drugs is so much beyond this it is frightening. I appreciate your interest. I think you are pushing us to do exactly the right thing.

Senator HARKIN. I really believe that is another thing that we have got to look at. Absolutely. Perhaps we will get into that at some point later on. In fact, I think you are right. We have to look at that.

Do not get me started on advertising and stuff like that for prescription drugs.

RENTAL EQUIPMENT AND SERVICE OPTIONS

I was looking at something here that had to do with the rental equipment and service options. I believe you got into that, right, Ms. Rehnquist?

Ms. REHNQUIST. Yes, we have.

Senator HARKIN. And you were pointing out that in many cases Medicare was paying for these service options and the purchase options that they had and that they could save a lot of money by eliminating the purchase option under the capped rental category of equipment.

Ms. REHNQUIST. I think what we were pointing out was the service contracts, like in retail, if you go to Circuit City and buy an extended warranty on a piece of equipment.

Senator HARKIN. Right.

Ms. REHNQUIST. What we found was that the Medicare program would save I think it is like $100 million a year if it would simply perform repairs when needed on equipment and not buy these extended warranties, if you will.

Senator HARKIN. Right.

Ms. REHNQUIST. Because then it is like an insurance company buying insurance. It just does not make any sense. We found that they would just save money making repairs on equipment as necessary because in these extended warranty options——

Senator HARKIN. Do you need legislation to do that, Mr. Scully, or can you do that?

Ms. REHNQUIST. Yes, and CMS concurred with our report. But yes, it does require legislation.

Senator HARKIN. It cannot be done regulatory-wise.

Mr. SCULLY. I think we tried to drop the lease extension option a few years back and were prohibited from doing it. So, I think we do need legislation. This is basically the issue. Basically after 13 months, I believe the patient has an option to buy and if they do not, there is a lease and there is a 20 percent of the lease cost maintenance payment after that in perpetuity. And we tried to end that a number of times without success. And I think that is very good policy.

Senator HARKIN. Well, again, I hope to work with you to craft legislation. I am open for suggestions that you might have for this. I think the Inspector General said that there were four different reforms to payments that they could save about $550 million a year. I assume all of those require legislative changes. So, my question then is for both of you. To the Inspector General, will you work with us and work with Mr. Scully to craft this legislative language to achieve these savings?

Ms. REHNQUIST. My office would be happy to do whatever we can do to help bring that along.

Senator HARKIN. Mr. Scully?

Mr. SCULLY. Absolutely. We have had tremendous cooperation with the Inspector General's Office in the year I have been there. We would be happy to do that.

Senator HARKIN. Well, that would be good. I think we ought to get that language ready to go this year. There is most likely going to be some bill on Medicare this year.

Mr. SCULLY. I certainly hope so.

Senator HARKIN. Something.

Mr. SCULLY. As do the doctors in the Puget Sound area.

THE FOUR REFORMS

Senator HARKIN. Something is going to be moving on Medicare and these are some of the minimal things that we have got to get included.

These four reforms. Was one of those competitive bidding? Was that one of the four reforms you were talking about?

Ms. REHNQUIST. I do not think so.

Senator HARKIN. That is right. The four reforms you were talking about were the maintenance payments for capped rental equipment we talked about, respiratory assist devices, prescription drugs used with medical equipment, albuterol and the other one was ipratropium bromide. Those were four.

Mr. SCULLY. I think all of those are involved in the competitive bidding demo. I know the nebulizer, albuterol—that is in the demo I think.

Senator HARKIN. Well, those four items and some of those are in competitive bidding, some may not be. We need to work with you to get language ready for the bill this year on those, and I would appreciate working with you on that.

Mr. Scully, what steps have you taken to respond to GAO's recommendation on using the UPN's, the universal product numbers, on Medicare claims to get better information about the specific products that Medicare is paying for?

That was another thing that goes back a long time, getting specific information on products. Everything has a UPN, I think, in the world. I do not know, but when we tried to find out how many, there just was not that information.

Mr. SCULLY. Well, the codes we pay under, which GAO pointed out are pretty broad—we basically have a wheelchair code and we pay for——

Senator HARKIN. Why not use a UPN code for every item? That way you have got all the data you need. Is that what you were getting at, Ms. Aronovitz?

Ms. ARONOVITZ. Yes. It would be quite an undertaking to look at all of 1,900 groups of products, but CMS could start with ones that they know are overpaid and obtain UPN information on the products within those categories. CMS should start small and focus inherent reasonableness activities on product groupings where it is known that overpayments likely occur. The first and fundamental issue is for CMS to know what products it is paying for, and what products are actually being delivered to beneficiaries. The second thing is to know what the price of those items should be. After obtaining those pieces of information, it is a matter of having the courage and the foresight to move forward, use inherent reasonableness, be able to defend the prices that the Agency would like to pay, and then execute these rates.

Mr. SCULLY. Mr. Chairman, can I just raise—since you are our appropriator, the number one barrier to us doing this well, to be honest with you, is that when we save money from the trust funds like the demo in Polk County or the other demo in San Antonio, we save money to the trust funds on the entitlement side, which goes to the Finance Committee, the Ways and Means Committee. The money to run the demos comes out of our domestic discretionary appropriations account, and that cost us about $17 million, $20 million last year. The committee said, do these demos, and we had to come up with the money to do them. And not to complain, because I am a cheap former OMB guy, but as we——

Senator HARKIN. I was going to say, can you help us with OMB, Mr. Scully?

Mr. SCULLY. Well, it is not just OMB. Again, I am not complaining about our budget, but I am saying the fact is we run a $260 billion Medicare program on a $2.5 billion administrative budget. About a $1.5 billion of that—most of this is done by the contractors. The contractors are largely the Blue Cross plans—run a huge program, $260 billion on $1.5 billion in domestic spending, and we go out and tell them—you know, a lot of this is really the DME carriers and the DME contractors. And we just do not have the bodies or the money to do a lot of this.

For example, if we go out to do competitive bidding nationwide, I mean, the tradition would be the committees will tell us, do competitive bidding, save all this money in DME, and there will not be any appropriated money for us to have the staff to do it. The reality is it is going to be extremely expensive to do.

I think fundamentally we have a lot of demands to save money for the trust funds.

COMPETITIVE BIDDING

Senator HARKIN. I think OMB ought to account those savings to this side of the ledger. It has been one of our frustrations in the past, that we get these savings, but it is never really counted as savings to us. It would be very helpful. I have made that argument to OMB for years, probably back when you were there. For me it does not make sense. It should be counted that way, but we have never been able to get OMB to do that under any administration, whether Democrat or Republican or whatever. We have never been able to get that done. But any help you can give us on that——

Mr. SCULLY. I will be happy to work with you on it. For example, when the Justice Department makes collections on recoupment in Medicare cases, a certain part of that goes back in the Justice Department. I think you can make an argument in some of these cases that if you want us to do more things on competitive bidding to save money for the trust funds, we just do not have the capability to do it right now.

There is a lot of push from the committees about putting in the BIPA reforms. If you have a Medicare appeal, it takes 2 years now, and there is a very rational reform policy that has been out there for 2 years, but we have not funded it because I do not have the money to do it. It is ridiculous that Medicare beneficiaries have to wait 2 years for their claims to be appealed, but we do not have the financing to reform the system. It is just a reality. The authorizing committees authorize things and then the money to make them happen is not appropriated, and there is a disconnect. I am just making that commentary.

Senator HARKIN. If we get OMB to score us the savings, we could probably do a lot more.

Mr. SCULLY. I will be happy to work with you on it. Thank you.

Senator HARKIN. All right. Well, listen, thank you all very much.

What I got out of this hearing is, first, the proposed regulations on inherent reasonableness are out of your shop and they are being reviewed now at the OMB level. And we are going to push as hard as we can to get those done. I cannot see any reason why they could not have them done in a month if they have been out of your shop for some time. I did not get exactly when they came out of your shop, but it is about time we get those.

Second, the administration will continue to press ahead this year on any Medicare legislation to start the competitive bidding process going and enact that.

Third, you are going to work with the IG's Office and hopefully with us to draft some proposed language in any legislation we might get up this year—and it might be soon. It might be happening this summer, so time is of the essence here—to address a couple of the problems that the IG came up with on some of the things like the service contracts and things like that.

Did I miss anything? I think that is it.

Well, I am encouraged. I am more encouraged now perhaps than I have been at any time in the past because, A, the administration is now supporting competitive bidding. That sure does help. Second, we have jumped through every hoop, the demonstration programs, the GAO investigation. Hopefully, there is not going to be another roadblock thrown up again this year to say that we have got to do another study. We have done enough studies. We have got to go ahead on this.

Thank you all very much for being here. Again, I thank you, Inspector General, for your great work. Thanks, Mr. Scully.

Next we will turn to the supplier side of this equation, and we will hear from Mr. David Williams, who is Director of Government Operations for Invacare Corporation, which was mentioned earlier, the largest manufacturer of home medical equipment in the country. Prior to joining Invacare, he served as a senior policy advisor to the Governor of Ohio on health and disability policy. Mr. Wil-

liams is also a member of the board of directors of the American Association for Home Care.

Mr. Williams, I did not get a chance to read your statement, but please go ahead. It will be made a part of the record in its entirety. Please proceed as you so desire.

STATEMENT OF DAVID T. WILLIAMS, DIRECTOR, GOVERNMENT RELATIONS, INVACARE CORPORATION

Mr. WILLIAMS. Well, trusting that you will read it, I will not read it to you and bore you with it, but I will summarize it if I can.

Mr. Chairman, I am honored to have the opportunity to testify before you and present what nominally could be the other side of the funding issue. You will note in my written statement that I did not—before I go on, I do want to acknowledge that two representatives of the industry, Tom Connaughton, who is the President and CEO of the American Association for Home Care, and Kimberlie Rogers-Bowers, who is on the Regulatory Affairs committee of our trade association, are here with me today. If you have some tough questions, I will punt, if you do not mind.

Senator HARKIN. All right.

Mr. WILLIAMS. You will note in my written testimony that I did not mention the data the OIG included regarding Medicaid retail sales and FEHB comparisons. I would be happy to do that, but I kind of focused on the VA. But I would like to get into the other in Q&A, if you do not mind.

I really want to make three points to the subcommittee to illuminate what I consider to be the inaccuracies in the report, but before I do, I want to make sure that you, Mr. Chairman, and all the members of the subcommittee know that the home medical equipment—you call it durable, we call it home medical equipment—services industry—we acknowledge that there must be a fair and accurate mechanism in place to ensure that the Medicare program is not being overcharged for the goods and services we provide. In other words, we do not oppose a reasonable IR rule that is reasonably implemented.

The problem in the past is that the inherent reasonableness rule was either applied unreasonably or used unreasonable data, and both the GAO and the Inspector General have supported the industry in that in the past. And that was the reason it was suspended while they worked at refining the rule to make sure that the data used in inherent reasonableness was fair and accurate, in other words, apples-to-apples comparisons.

While we accept inherent reasonableness, I also want to point out that inherently reasonableness does not necessarily equate to the price that Medicare pays, inherently reasonable only if it equals what the VA pays or even what Medicaid pays or that FEHB pays because again there is a difference there.

It is important to remember that when we talk about DME in the Medicare program, that we are not talking about a commodity. You showed a picture of a commode. That commode comes with the provider delivering it to the Medicare beneficiary, setting it up—believe it or not, if you look at that picture closely, you will see the legs are adjustable, and there are parameters for those legs to be adjusted—and showing the patient both how to maintain it and to

use it. There is a safe way to get on that commode and an unsafe way. So, they actually train the patient to do it. So, we have got delivery, we have got set up, we have got training. Then we have got the Medicare costs of billing associated with that commode.

So, there is a whole lot more that goes with that commode than just the product in the picture, and it makes no difference whether we are talking about that commode or nebulizers, respiratory therapy using nebulizer drugs, or motorized power wheelchairs. They all have a huge, huge service component.

The respiratory drugs, for example, with a nebulizer. I told you what happened with the commode. With the nebulizer, under Medicare rules, the provider goes out and again delivers the nebulizer to the patient with a respiratory therapist to instruct them how to use it and then has to follow up on a regular basis with the patient with a trained respiratory care specialist to make sure that the patient, A, is complying and, B, still needs to machine. We are required to do that under Medicare.

Rehab technology is something that is pretty close to me, as you will note. The Rehab Council, the professional organization representing the rehab, did a study recently and found that just before the wheelchair is delivered, like the power wheelchair I am sitting in today, before it could be delivered to me, there are 35 hours of professional service time involved in evaluating me to make sure I have the right equipment, getting the right equipment, adjusting the right equipment, programming the equipment, training me how to use the equipment, then reevaluating me to make sure it works right.

To do a power wheelchair right, we have to send somebody out to the beneficiary's home to evaluate the home to make sure that the product we provide will work in their home. And then in the first year afterward, we find that on average we spend about 5 to 6 hours reprogramming the product, just going back and reassuring the beneficiary. I know it looks pretty smooth when you see somebody like me who has been in a chair for 25 years, but the first year in a power wheelchair is hell. I can take you to my home and show you the damaged woodwork to prove that fact.

So, again, none of these examples include what Medicare has acknowledged time and time again, which is the cost of doing business with Medicare which is both the cost of the billing process which is hugely expensive because of the amount of paperwork and documentation involved and the cost of money, if you will. The provider has to buy this power wheelchair from Invacare at a price of about $7,000 and wait in most cases 5 to 6 months to get their money back. There is a cost associated with that money. They are paying interest on it either to us or to a bank or to a credit card or something.

The next point I want to make is the fundamental difference between the VA health system and the Medicare program. As has been said, Medicare is an insurance plan. It is just like Blue Cross Blue Shield and everything. It purchases goods and services through private providers on a patient-by-patient basis. The Medicare fees for DME include the costs of all the services that I mentioned, as well as those associated with the actual price.

Again, it is important to note that 70 percent of the home medical equipment service providers who service Medicare beneficiaries are small businesses. And in Iowa, just to make a point for you, that number is 85 percent. The vast majority are small business, and they purchase supplies and equipment on an as-needed basis. They do not keep a ton of product in a warehouse that they can ship off and buy in huge quantities to get the kind of discounts that, for example, the VA does.

On the other hand, the VA medical program is conducted by a fully integrated, Government-owned and operated health system. As a manufacturer, we sell our products directly to the VA on a national contract. I know we have talked about competitive bidding. They have a fee schedule that comes out, the national contract that comes out. Under Federal law, we have to as a manufacturer—for example, if a large national provider comes to us and negotiates a lower price, automatically our price to the VA goes down under Federal law. So, we have to make a decision, are we going to continue to provide, say, K0011 power wheelchairs to the VA at the price that it went down to because a contract changed with a national provider. And there are a lot of business decisions in there, but you have to understand that that is the lowest possible price.

And it disregards volume. We could have a national provider—there is national chain, for example, that would buy more product than the VA in that category, K0011 power chairs, but even though they buy more, the VA would get the lower price than they get even though they buy less. So, there is a fundamental difference in the way it happens.

More importantly for the VA is the fact that—like Kimberlie's company, they provide the respiratory therapist that goes out and makes the visits. They provide the delivery truck and driver who delivers the commode. They provide the physical and occupational therapist who do the evaluations and fittings and all the follow-up on the power chair. The VA does that with existing staff and existing infrastructure. So they pay the price for the product. They pay our wholesale price. It is a fundamental difference.

And another big difference with the VA is that there is no billing cost associated with it. The cost of doing business with the VA is waiting to get your check from the Government which is relatively quick.

In order to come up with the true cost of what the VA pays for DME, you would have to amortize the costs of that entire infrastructure, the employees, all the physical infrastructure, determine what percent of it is associated with the DME benefit to veterans and then add that percentage to what you are paying for the actual product. Then you begin to understand what the true costs are. To compare the VA to Medicare is really, as has been said earlier by the GAO, an apples and oranges comparison. So, that is very important.

Again, I want to say that we do not object to having mechanisms in place to set Medicare fees at reasonable levels. However, we do strongly feel that the only way to determine what is inherently reasonable is to make inherently reasonable comparisons. It is inherently unreasonable to state that Medicare fees for DME are too high just because of what the VA pays is less.

I believe that the OIG has done a disservice to this subcommittee and, more importantly, to Medicare providers and beneficiaries by publishing a report that is both inaccurate and invalid because of the comparisons it makes. With all due respect to the IG, she has reached these conclusions because of the comparisons made and the validity of the data. Some of the data showed up in earlier reports.

For example, in the 1999 information that came up that was a result of the suspension of the IR rule, on enteral nutrients they compared what Medicare was paying for prescription enteral nutrition, what you put in through a feeding tube, to Ensure, which they bought off a drugstore shelf, maybe at Costco. Now, there is an apples and oranges. On catheters, they went to a wholesaler and just sent in and looked at a box of catheters and said, what does this box of catheters cost, and then compared it to the Medicare price. It turned out that the product that they compared was out of date and could not be sold in this country because it was not considered to be sterile. So, we need to make sure that there always is valid data.

I respectfully ask and our industry asks that you reject the OIG's report but instruct the Centers for Medicare and Medicaid Services to use its IR authority judiciously and to base all decisions on accurate and appropriate data and comparisons.

It is important to remember that the model used to deliver services to Medicare beneficiaries is the same model, Mr. Chairman, that you would receive DME, should you need it, through the Federal Employee Health Plan. Many of them are managed care plans and so forth, but they contract with private providers and they include in the price the services. So, it is important that you realize that that one fee is paid for a combination of quality products and the associated services needed to achieve the clinical outcome you expect and your doctor expects when they write the prescription. Under Medicare, DME is not a commodity. It is a combination of goods and services. I cannot express that strongly enough.

You asked us to answer your question in the beginning why HHS does not take advantage of VA type buying power and why it will not work. I just jotted down a few things that I would point out to you that are different between the HME providers serving Medicare beneficiaries and the VA system.

The HME provider is a small business that must comply with 21 supplier standards. They must be accredited in order to operate their business, which requires having a strong compliance plan and a strong training and education plan within their business, and they must pay the cost of staff licensure and credentialing. For example, that occupational therapist that is involved in fitting and measuring for the power wheelchair has to have continuing education every year and they must pay that cost. The VA absorbs that cost if they used a licensed occupational therapist. That respiratory therapist has to be licensed in the State that they work in and so forth. So, there are some fundamental differences in the model.

The second point is that one of the things that has not been brought up here—it was touched on, but not brought up and you mentioned when you mentioned the UPN, universal product num-

bers. One of the reasons Medicare is in this conundrum right now is the gross inadequacy of the HCPC coding system as it is used for the DME benefit. In one product used in your comparison, for example, the K0011 motorized power wheelchair, there are products in that category that Invacare manufactures that the manufacturer's suggested retail price is $4,200, and there are products in that category, because of their complexity, the technological advancement, and their application, cost nearly $8,000. They are all in the same category. So, how do you come in and say Medicare is paying too much when what you are comparing to has such a breadth? The coding system is grossly inadequate and I submit you cannot really even begin to make comparisons until you have the coding system fixed.

Finally, I just want to close. You have talked about competitive bidding a lot, and I want you to know that our industry welcomes true competition. We really do welcome true competition. But I want to point out the difference between competitive bidding and the competitive bidding demonstration.

In competitive bidding, which our customers engage in with health plans all the time, they know how many covered lives that they are going to get, the approximate utilization so they can make a business decision in their bid. They know the volume, they know the potential volume, the up side, the down side, the demands, and all the parameters.

The competitive bidding demonstration in Polk County and San Antonio, bidders came in and then they took the lowest bid. And then they said, okay, anybody who bid, even if you were higher, if you are willing to do it for this lowest bid, you are in. That is not competitive bidding. That is Government-sponsored price setting by any stretch of the imagination.

And despite all of the flowers that have been laid at the foot of those two demonstrations, as the GAO pointed out, they still do not know the cost of it. We do not know the associated costs because you do not look at how many people have been readmitted to the hospital because they did not get the appropriate follow-up by a respiratory therapist in Polk County, Florida. It has happened, Mr. Chairman. What has happened in Polk County, despite the suggestion that it did not, is by the end of the second round, 73 percent of the respiratory care in Polk County, Florida is provided by one company. Lots of small businesses went out of business, and the level of service is diminished, and when the level of service is diminished on respiratory care, people get sick and are readmitted to the hospital. That never shows up on your score sheets.

PREPARED STATEMENT

So, my statement is probably more lucid than my oral comments.

Senator HARKIN. No, it is very good, a good statement.

Mr. WILLIAMS. I would be pleased to answer any questions that you have.

[The statement follows:]

PREPARED STATEMENT OF DAVID T. WILLIAMS

Mr. Chairman, Members of the Subcommittee; my name is David T. Williams and I am the Director of Government Relations for Invacare Corporation. Invacare is the

world's leading manufacturer and distributor of medical equipment and supplies for use in post acute care. Most of the products in our various catalogues are covered under the Medicare DME benefit.

I am honored to have the opportunity to testify before you today to present the "other side" of the issue of Medicare payments for durable medical equipment (DME). My statement today will be brief and I respectfully ask that it be entered into the record of today's proceedings.

I want to make three points to this Subcommittee that illuminate the inaccuracies in the information contained in the report from the Inspector General. Before I do, I want to make sure that everyone on this Subcommittee knows that the home medical equipment services industry acknowledges that there must be a fair and accurate mechanism in place to insure that the Medicare program is not being overcharged for the goods and services that we provide. However, I also want to point out that "inherently reasonable pricing" under Medicare does not equate to fees that are equal to what the Department of Veterans Affairs pays, for what appears to be the same products.

The first point I want to make today is that DME is not a commodity. It is a combination of a product and the services necessary to get the desired clinical outcome for the patient. It does not matter if you are talking about a walker, home respiratory therapy using a nebulizer or a motorized/power wheelchair—there is a significant service component included in the Medicare payment for each of these products.

An HME provider must deliver, measure, adjust and train the beneficiary in the proper use and care of a walker under Medicare. The same goes for a nebulizer with the additional responsibility of having a trained respiratory care specialist visit the patient on a regular basis to check their progress and document compliance with the physician's orders. The Rehab and Assistive Technology Council of the American Association for Homecare conducted a survey that shows that on average, proper evaluation, fitting, adjustment, training and delivery of a motorized wheelchair takes 35 hours of trained professional service time before the power wheelchair is delivered. During the first year, the rehab provider can expect to spend another 5 to 6 hours in making additional adjustments in the programming and seating of the unit. Note that none of these examples include the significant amount of effort and time required to submit a claim for home medical equipment services under Medicare.

The next point I want to make is the difference between Medicare and the VA Health System when it comes to the DME benefit.

Medicare is an insurance program just like any private health insurance company. It purchases goods and services through private providers on a patient-by-patient basis. Medicare fees for DME include the costs of all the services associated with the actual product. Seventy percent (70 percent) of the home medical equipment service providers who serve Medicare beneficiaries are small businesses that purchase supplies and equipment on an as-needed basis.

The VA medical program is conducted by a fully integrated, government-owned and operated health system. Manufacturers sell their products directly to the VA on a national contract. Under federal law, the VA receives the lowest contract price the manufacturer sells it products for to any of its customers, regardless of comparative volume.

More importantly, the VA Health System provides the services required for successful outcomes using its existing infrastructure and staff. The VA costs sited in the OIG's report reflect the cost of the product only and that amount is the lowest price available. Employees of the VA do product delivery. Therapists and technicians employed by the VA do all evaluations, fittings, patient training and adjustments. Respiratory therapists employed by the VA visit veterans requiring respiratory medications delivered by nebulizers. Finally, there are no billing costs associated with providing DME through the VA Health System.

In order to come up with the true costs of items of DME provided through the VA, this Subcommittee would have to amortize all the costs of the federal employees working for the agency as well as the costs of its vast physical infrastructure. It would then have to determine and assign a percentage of these amortized costs to the price paid for each item of DME it dispenses. These would be the true costs of DME provided through the VA Health System.

Mr. Chairman, Members of this Subcommittee; let me say again that the HME services industry does not object to having a mechanism in place to set Medicare fees at inherently reasonable levels. However, we do feel strongly that the only way to determine what is inherently reasonable is to make reasonable comparisons. It is inherently unreasonable to state that Medicare fees for DME are too high based on a comparison with what the VA pays for the same products. I believe that the

OIG has done a disservice to this Subcommittee and, more importantly, Medicare providers and beneficiaries by publishing a report that is both inaccurate and invalid.

With all due respect, the OIG report has reached invalid conclusions because it has based its findings on an "apples to oranges" comparison. On behalf of Invacare Corporation and the entire HME services industry, I respectfully ask that you reject the report the OIG presented today and instruct the Centers for Medicare and Medicaid Services to use its inherent reasonableness authority judiciously and base all decisions on accurate and appropriate data and comparisons.

Finally, I want to remind each of you that the way Medicare administers the DME benefit is the same way DME would be provided to each of you, should you need it, under the Federal Employees Benefits Program. One fee is paid for quality products AND the associated services necessary to achieve the clinical outcome that you and your physician would expect. Under Medicare, DME is not a commodity. It is a combination of goods and services for which providers have a right to be adequately and fairly compensated.

Thank you for giving me the opportunity to testify this morning and I would be happy to answer any questions you may have for me.

Senator HARKIN. Well, thank you. That was a good presentation. I listened intently.

I think my history and my record will show that I take a back seat to no one in support of quality of care for people with disabilities, but I want you to know I have been down that road a lot of times. Again, I would just point out one example, and that is oxygen. I cannot tell you how many times I met with oxygen suppliers back in the 1990's when we were working on this. It is an item that requires services. It requires visits. It requires all kinds of things that you just mentioned. And they protested loudly that it just could not be cut because of all these services that were required for oxygen. We cut it by 30 percent. We just cut it by 30 percent. Then we put out for bids, and they came in and bid 16 percent lower than that for oxygen with the services.

So, again, that example informs me a lot about what might be out there. Oxygen is the largest category of medical supplies paid for by Medicare. And again, it requires a lot of services also.

Mr. WILLIAMS. Mr. Chairman, I believe if you do check in Polk County, you will find that there is a reduction in service and that the level of professional care is greatly diminished.

Senator HARKIN. If you want to have some input on that, I would be glad to take it.

Mr. WILLIAMS. We will provide you with it.

Senator HARKIN. According to GAO, that is not the case. So, we have a disagreement there.

Now, again, I would say, Mr. Williams—and I mentioned this earlier—that there are going to be devices, equipment, different things that because of a specialized need and specialized types of settings are going to require a different level of reimbursement. That is why I start at the bottom. We do the competitive bidding, and if it requires something special, then you have inherent reasonableness to pick it up. I understand that there are going to be those kinds of items.

But you just cannot tell me that it requires some special kind of services to teach people how to use a saline solution. I am sorry. On these blood glucose monitor strips that they bought from Costco, right now they threw in 25 lancets free. Medicare is paying for those. They are paying through the nose for the strips too.

You may come and say that there are certain pieces of equipment, whether it is motorized wheelchairs and other kinds of things that require something different. I will grant you that. But you cannot convince me that is true of blood glucose test strips, lancets, saline irrigation solution, a walker.

Mr. WILLIAMS. I would disagree with you having had the experience of having to use a walker.

Senator HARKIN. Well, I will disagree with you too. I just had a brother that had to use a walker, and his services and his instruction on how to use it did not come from the people who made it. It came from the therapist associated with Mercy Hospital in Des Moines who taught him how to use it. It did not come from the company. I was there. It was the therapist who adjusted it, got it. Medicare paid for the walker. There is no doubt about that. I do not know who made the walker.

Mr. WILLIAMS. Medicaid?

Senator HARKIN. Medicare paid for it. But there was not anyone from the company coming out doing anything.

And then pressure pads. There may be some things that are associated with services, but I do not think it warrants paying three times more than what the VA is paying. Plus, I am also informed that in some of these cases where VA is paying for these, they are also getting the services. VA pays for them. You have a veteran living at home. The services go to that veteran. They paid this. They get the same services that a Medicare person gets.

Mr. WILLIAMS. They get paid additional. Mr. Chairman, for example, if the VA had a—let us take the bed in Iowa and because they did not have a distribution center there, they may go to a local provider and say, would you deliver a bed to Veteran Jones in a small town because he is not close by. They will pay the VA price for the bed. They will also pay a delivery fee and they will pay a setup fee. They will provide additional amounts plus the price of the bed from the fee schedule.

Senator HARKIN. We found out that the Department of Veterans Affairs, in providing the oxygen, required the same services as provided by Medicare, exactly the same. This was not some additional add-on. The Veterans Administration said here is what we pay for the oxygen, and included in that must be all these services. It was not an add-on. And we got a 30 percent cut in that.

So, I do not know. Maybe there are some add-ons. I will look at it. Maybe the VA says, okay, we will pay for this, but then we will pay additional services. But the one that I am most familiar with, oxygen, it was the same services.

Ms. ROGERS-BOWERS. [Inaudible.]

Senator HARKIN. I am sorry. Would you identify yourself for the record please?

Ms. ROGERS-BOWERS. My name is Kimberlie Rogers-Bowers and I sit on the American Association for Home Care's Regulatory Committee. I was also very much part of the review of the GAO report when the oxygen was analyzed. Actually with the VA study, I understand that there were additional add-ons for the portable system and for the portable refills and also a delivery charge in some cases.

Senator HARKIN. That may have been just for the portable one, maybe. But for the ones in the home, I do not think so.

Ms. ROGERS-BOWERS. For the additional portable system, if a patient was portable, as well as any refills that the patient was receiving, there was an additional add-on for that, as well as in some cases delivery charges, which we can pull that information and send it to you.

Senator HARKIN. Why do you not get that information to me. I will be glad to take a look at it.

[The information follows:]

PREPARED STATEMENT OF THE AMERICAN ASSOCIATION FOR HOMECARE

The American Association for Homecare (AAHomecare) submits the following testimony to the Senate Subcommittee on Labor, Health and Human Services, Education and Related Agencies in response to the updated comparison of Medicare payment rates to other payers for certain items of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). AAHomecare represents all segments of the homecare industry, including providers and suppliers of home health services, durable medical equipment (DME) services and supplies, infusion and respiratory care services and rehabilitative and assistive technologies. Many of the individuals our members serve are Medicare beneficiaries.

In its most recent examination of Medicare payments, the Inspector General of the Department of Health and Human Services (HHS) compares the Medicare payment rate for sixteen items of DMEPOS with the rates paid by the Department of Veterans Affairs (VA), state Medicaid programs, retail establishments and the Federal Employee Health Plans (FEHPs). The OIG review is a rehash of its previous studies, essentially reaching the same conclusions without addressing any of the systemic differences between the programs it compares. The OIG contends that its conclusions support its previous findings that CMS could achieve significant savings by adopting any of the alternative payment systems of the four programs listed above. However, in this recent comparison—as in the OIG's previous studies—it fails to account for the structural differences in the programs and the additional administrative costs of providing DMEPOS to Medicare beneficiaries, which are described in greater detail below.

THE OIG'S COMPARISON OF MEDICARE TO OTHER PROGRAMS IS FUNDAMENTALLY FLAWED

Comparing the VA to Medicare is like comparing apples to oranges. The fundamental differences between the methods used by the VA, Medicaid, the FEHP or retail suppliers and Medicare suppliers to purchase, deliver and get paid for items of DME and supplies render it inappropriate to compare payment rates between them. The industry has higher administrative costs when servicing Medicare beneficiaries than it does other patient groups. Medicare providers spend a significant amount of time and money filing claims for Medicare reimbursement and obtaining documentation to support the claim. The differences between the Medicare program and the VA have, for example, been recognized by the GAO[1] and the OIG, and the OIG has held that the higher costs of servicing Medicare beneficiaries can justify higher charges to Medicare by suppliers.[2] Suppliers must document the medical necessity of each claim, obtain a prescription from physicians, often must request portions of the beneficiary's medical record to document medical necessity and must document proof of delivery. Providers also incur the expense of billing and collecting Medicare co-pays and deductibles and bear the risk of bad debt.

Moreover, VA payment amounts do not reflect the costs for delivery of the items because they are absorbed under other parts of the VA budget. The VA purchases items directly from manufacturers and distributes them to beneficiaries through the VA facility network. Unlike most homecare suppliers, the VA can purchase directly from manufacturers in large quantities. There are many small homecare suppliers that may serve only two or three hundred beneficiaries each year. The VA, in contrast, can commit a large volume purchase to a manufacturer.

---

[1] Comparison of Medicare and VA Payment Rates for Home Oxygen, Letter dated May 15, 1997 from William Scanlon, Director, Health Financing and Systems Issues, GAO to William Roth, Chairman of Finance, United States Senate.

[2] See OIG Advisory Opinion, No. 98–8.

In contrast, Medicare suppliers provide beneficiaries with services and delivery of the items that are not directly reimbursed by the Medicare program. Transaction costs for servicing Medicare beneficiaries are higher than they are for VA patients because of the significant cost of complying with Medicare program rules. Medicare suppliers must meet twenty-one supplier standards which include maintaining a physical facility, delivering items to the beneficiary, providing education to the beneficiary and maintaining a complaint resolution procedure.[3]

The OIG attempts to address the disparities between the VA and the Medicare program by incorporating a 67 percent mark-up from VA payment rates into its analysis. However, this mark-up amount derived by CMS bears no relationship to a provider's costs of furnishing DMEPOS items. CMS calculated the percentage based on the suggested retail price for items in the manufacturers' requests for HCPCS codes spanning over ten years. Not only did CMS use stale data, it did not undertake any analysis of the costs to providers of participating in the Medicare program. The 67 percent figure is arbitrary and should not be given any weight as a benchmark for Medicare payment amounts.

THE MEDICARE PROGRAM CAN NOT BE DIRECTLY COMPARED TO OTHER PUBLIC OR PRIVATE INSURANCE PROGRAMS OR RETAIL ESTABLISHMENTS

The OIG also compares Medicare payment rates to state Medicaid programs, the Federal Employee Health Plans and retail operations. These comparisons are equally flawed because they compare Medicare to drastically different health care delivery models.

—Medicaid programs vary widely by state and it is therefore imprecise to compare Medicare reimbursement rates to an amalgamation of Medicaid rates. For instance, some Medicaid programs have large participation by managed care companies. In addition, many Medicaid programs offer a simpler, more predictable administrative framework which include mechanisms like prior approval which streamlines the reimbursement process and guarantees that the supplier will be paid for the items it provides.

—Many Medicaid programs have regional concerns that affect the payment for DMEPOS in that state. For instance, the Wisconsin Department of Health and Family Services recently responded to an investigation by the Office of Inspector General (OIG) for the Department of Health and Human Services (HHS) that found that the Wisconsin Medicaid program could save money by reducing its reimbursement rates for oxygen to the Medicare rate. In refusing to accept the OIG's recommendations, the Department stated: "while we agree with your conclusion that Wisconsin Medicaid pays more than the Medicare rate, we disagree with the recommendation that we reduce our payment level to match Medicare. It remains our belief that such a reduction would result in the refusal of providers to serve Medicaid clients. It should be noted that many of the fiscal disparities that resulted from the 1997 Balanced Budget Act have been identified as causing a loss of providers, and that many of those limitations have since been rescinded. Therefore, we intend to maintain the level of reimbursement that we believe is appropriate for our state."[4]

—Retail prices do not account for the services associated with delivering DMEPOS items to Medicare beneficiaries. The service levels for retail or internet suppliers are extremely low or nonexistent when compared to those of Medicare suppliers. Medicare suppliers provide many additional services as part of delivering items to a beneficiary including patient education, clinical monitoring and care management. Medicare suppliers are required to meet twenty-one supplier standards, which include requiring a supplier to deliver items to a Medicare beneficiary, while retail customers must pick-up their items. These additional costs are not accounted for in the OIG report. Importantly, however, even considering the disparity in services levels between Medicare DMEPOS suppliers and retail establishments, the OIG found that the Medicare median is actually lower than the retail median for six of the sixteen items examined, with an additional four items having only a nominal price discrepancy.

—The OIG's comparison of Medicare payment to the Federal Employees Health Benefits Plan (FEHB) is flawed because it compares two drastically different health care delivery models. FEHB is a health insurance program that includes many managed care companies. Managed care entities typically contract with

[3] See 65 Fed. Reg. 60366 (October 11, 2000).

[4] Department of Health and Human Services Office of Inspector General, Review of Medicaid Payment Amounts for Oxygen Related Durable Medical Equipment And Supplies, Wisconsin Department of Health and Family Services, Madison Wisconsin, October 2001; A–05–01–00031, (OIG Study).

suppliers for negotiated rates and guarantee a certain number of enrollees in return for the contracted rate. The administrative burden of servicing managed care enrollees is lower than dealing with the Medicare program. Generally, enrollees in these kinds of plans have more limited choices of suppliers than do Medicare beneficiaries. Managed care companies offer streamlined processes like prior approval which reduces the days sales outstanding, and the burdens of certifying medical necessity and collecting reimbursement.

NEITHER COMPETITIVE BIDDING NOR INHERENT REASONABLENESS ARE VIABLE PAYMENT METHODOLOGIES FOR THE MEDICARE PROGRAM

The OIG has advocated the use of competitive bidding or inherent reasonableness as a method for reducing the prices that Medicare pays for certain DMEPOS items. Neither of these methodologies, however, accurately account for the full range of services associated with delivering the items to Medicare beneficiaries. In addition, both payment methodologies have serious structural and procedural flaws which would need to be addressed prior to CMS implementation.

The competitive bidding demonstration prices are a result of an artificially manipulated marketplace and therefore do not accurately reflect DMEPOS payment amounts that will sustain the level of services currently given Medicare beneficiaries. Although the four items analyzed by the OIG that were subject to the competitive bidding demonstrations achieved savings, it is too soon to fully understand the effect that these reductions will have on beneficiary access to critical services and choice of products. Competitive bidding may significantly reduce the services available to Medicare beneficiaries in the demonstration area. In fact, even CMS' in its January 2001 report "Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS, First Year Annual Evaluation Report" acknowledged that "[a]lthough we have learned a number of lessons from the evaluation so far, we caution that it is premature to make final conclusions about the long-term impact of the demonstration on many of the evaluation issues."

It is premature to make any economic assumptions based on the minimal amount of data coming out of the limited demonstration project. The costs of administering a national competitive bidding program are likely to offset any savings to the program. In addition to the reduction in services, competitive bidding would result in the elimination of small DMEPOS providers. This will result in a dearth of bidders when it is time to update or renew the bidding process. As a result, bid prices are likely to rise and patient choice is likely to diminish as more suppliers are eliminated.

CMS' use of IR authority is equally ill-advised given the serious procedural missteps in implementing the authority. CMS published an interim final rule with comment period in January 1998 implementing the authority granted in the Balanced Budget Act of 1997 (BBA 97). CMS did not respond to any of the comments submitted. Later that year, CMS issued a proposal to cut payments for eight groups of products. CMS issued another proposal for an additional round of cuts in August of 1999. Congress subsequently suspended CMS' IR authority pending a GAO study on the issue and the publication of a final rule.

The GAO report raised serious shortcomings regarding CMS' use of its inherent reasonableness authority including that CMS' data collection was not consistent and did not set out sufficient criteria. Because of the considerable amount of time that has passed since the initial rule was released and CMS' failure to respond to the comments submitted pursuant to the interim final rule, CMS should release a new inherent reasonableness rule for comment to allow a fair and full administrative process. In addition, prior to using inherent reasonableness, CMS needs to develop a process to ensure that any data used is statistically valid market data, develop a sound methodology and ensure an appeal mechanism for review.

CONCLUSION

In conclusion, Medicare payments should not and cannot be compared to the payments of the Department of Veterans Affairs, retail establishments or other private or public insurance programs because of the disparities inherent in the different health care delivery models. CMS should not use competitive bidding or inherent reasonableness to adjust payments until the procedural flaws in those methodologies are addressed.

Senator HARKIN. Well, I hear you and I understand that suppliers have an intense interest in this. I understand that. And I want to make sure we get quality products too. But the fact is we went from $23 billion where the GAO estimates that we were

spending down to about $12 billion in cutting a lot of these things out. Quite frankly, I have not heard any hew and cry from Medicare beneficiaries anywhere in this country that they are getting less services or less quality than what they got before.

I just think we need to tighten down on it a little bit more, and the administration agrees with competitive bidding. But I believe there ought to be inherent reasonableness to address the specific kinds of concerns that you have to make sure that those anomalies that might be out there or specific things that might require some special additional types of things are addressed. That is why I wanted to make it clear this morning in my questioning of the administration people, especially GAO, that they were not saying that with competitive bidding they could do without inherent reasonableness. I do not believe so. I believe it has got to be there.

But I am sure you saw my example earlier where I said you can take inherent reasonableness from the top down or from the bottom up. I think it ought to be from the bottom up. That is just my opinion after working on this for 12 years.

Mr. WILLIAMS. Mr. Chairman, I do not disagree with what you are saying. As long as IR is based on validated and valid comparisons, and as an industry, we do not even disagree on the issue of competitive bidding, so long as it is true competitive bidding where you can make reasonable business decisions and accurate business projections.

Senator HARKIN. Do you also agree we ought to have UPN's on every item?

Mr. WILLIAMS. Mr. Chairman, I do. We as a company do because you can get more information.

Senator HARKIN. You and I agree on that.

Mr. WILLIAMS. For example, that K0011 code, I mean, golly, geez, within that product alone, you are getting information on a code. For example, you were giving comparative information. We do not know whether they were comparing it for all the high-end products or what.

Senator HARKIN. That is right.

Mr. WILLIAMS. So, with the UPN's you are going to get that.

Senator HARKIN. That is right.

Mr. WILLIAMS. I really do believe that, and as a company we put it on everything anyhow because we have to. The VA requires it.

Senator HARKIN. I have to get from CMS what the cost would be associated with that. They indicated some costs. He did not know. But I believe that is something else that we are going to have to enact in legislation, that is a requirement of a UPN code on every single device. The technology is there. They can keep data storage systems for information like that. It is easy. So, I do not see why they cannot do it. That way we would have a better handle and better knowledge in comparisons of what we are talking about. I think that would better enable them to use inherent reasonableness also to address some of the issues you brought up.

Mr. WILLIAMS. I agree.

Senator HARKIN. Thank you very much. I appreciate it, Mr. Williams.

Mr. WILLIAMS. Thank you for your time, Mr. Chairman.

Senator HARKIN. Thank you for being here.

STATEMENT FOR THE RECORD

We have received the statement of the Advanced Medical Technology Association that will be made part of the hearing record.

[The statement follow:]

PREPARED STATEMENT OF ADVANCED MEDICAL TECHNOLOGY ASSOCIATION

The Advanced Medical Technology Association (AdvaMed) is the largest medical technology trade association in the world, representing more than 800 medical device, diagnostic products, and health information systems manufacturers of all sizes. AdvaMed member firms provide nearly 90 percent of the $68 billion of health care technology products purchased annually in the United States and nearly 50 percent of the $159 billion purchased annually around the world.

AdvaMed is pleased to present this written testimony on behalf of our member companies and the patients they serve. We understand Congress' and the Inspector General's concern regarding the differences in purchase prices between various government and private programs. However, we are troubled that the Office of the Inspector General (OIG) failed to use a rigorous study methodology that would adequately assess Medicare payment levels for the 16 products it reviewed. In fact, the OIG report stated: "This limited study was not designed to meet the rigorous inherent reasonableness standards for revising Medicare payment rates as defined by Section 4316 of the Balanced Budget Act of 1997."

AdvaMed supports the goal of seeking greater economy and efficiency in Medicare payment programs. We believe this is in the best interest of patients, the medical device industry, and the U.S. economy as a whole. However, we believe that there are important distinctions between Medicare, the Veterans Administration (VA), private insurers, and retail sales that Congress must recognize in assessing the various pricing structures. These differences deserve careful consideration before new mandates are imposed on Medicare.

To address any overpayments for medical supplies, we recommend that the Centers for Medicare and Medicaid Services (CMS) issue a new notice of proposed rulemaking with a comment period to describe the implementation of its inherent reasonableness (IR) authority, including provisions for conducting valid market surveys. With an open, collaborative, transparent, and responsive IR process, experimental approaches to cut payments, such as competitive bidding, would be unnecessary.

COMPARING MEDICARE TO THE VETERANS ADMINISTRATION

The OIG's June 2002 report "Price Comparisons for 16 Medical Equipment and Supply Items" reviews the difference in payment levels between Medicare and the VA for medical supplies. In comparing the payment values, we must also consider the significant differences between the two programs. The Medicare program is a health insurance payment program that is structured to pay for services provided by physicians, hospitals, suppliers, and other facilities, practitioners, and providers. Medicare does not directly provide any health-related services. The VA, however, is a direct provider of services through its hospitals and clinics. That difference is critical; and it directly affects the prices that suppliers can offer in at least five separate ways.

First, the VA itself provides some of the services that would otherwise be the responsibility of the supplier. As a direct provider, the VA offers storage, delivery, training, and other product-related services directly to veterans. As a result, since the suppliers do not need to offer these services, these costs are not factored into the prices of the products that the VA purchases. On the other hand, products reimbursed under Medicare must include the costs for these additional services so that beneficiaries can receive and appropriately utilize the products.

Second, there are billing efficiencies in supplying a program that is a direct central purchaser, rather than a reimbursement program. As you know, the VA includes a relatively fixed number of dedicated hospitals, clinics and patients, compared to the Medicare program. As a result, the VA can manage the contracting process centrally, and enter into exclusive contracts with suppliers. Even though the program is smaller than Medicare, the VA is large enough that its central contracts provide high volume, predictable purchase agreements, and one-step billing. That reduces the supplier's cost of administering the account. In contrast to the VA, Medicare cannot contract centrally for direct purchases because it is fundamentally set up to reimburse. Even the competitive bidding proposals we have seen in Congress to date, while they attempt to arrive at one price, do not change the program

to a direct provider approach and therefore do nothing to make the paperwork associated with a reimbursement system more efficient. Thus, even competitive bidding would not change the economics of serving the Medicare market, and in fact could make it more expensive.

Third, compliance costs are less with the VA. Medicare must pay providers to document the receipt and delivery of the product to the patient, the physician's order, the patient's diagnosis, treatment plan and anticipated course of the patient's disease.

Fourth, carrying costs are greater for Medicare. Medicare claims are paid months after the product is delivered to a patient, making Medicare transactions significantly more costly than those with the VA. For example, enteral nutrition is typically ordered for a patient during one month, and provided to the patient during the subsequent month. In the third month, documentation and claims paperwork for the preceding month is filed with the DMERC. Receipt of payment may be four months or more after the product is first purchased by the supplier.

Lastly, the OIG's study does not directly compare the same products in its analysis because the VA tends to buy different, less expensive products. Also, where products differ widely but share the same code, the VA can choose to contract for bulk supplies of the product that offers fewer features in the range of products available—yielding lower prices.

COMPARING MEDICARE TO OTHER CARE SYSTEMS

The Medicare program is not comparable to Medicaid or private insurers. One of the differences is the scope of the programs. Medicaid and private insurers have a much smaller population, with different characteristics from Medicare beneficiaries, a limited area, and the ability to develop purchasing relationships with local facilities, practitioners, providers, and suppliers.

The OIG study's methodology provides anecdotal, not statistically valid information comparing Medicare reimbursement to other payers, and likely overestimates the actual savings. In establishing the "median retail price," the OIG surveys only ten suppliers, but then simply extrapolates the results to apply to over a hundred thousand suppliers. For example, even if all ten suppliers surveyed provide blood glucose equipment and supplies, this would not be a statistically significant sample to predict nationwide for the nearly 20,000 blood glucose suppliers. We are concerned that these unscientific approaches can lead to inappropriate policy and a chilling effect on Medicare beneficiaries' access to medical technology.

COMPARING APPLES TO ORANGES—THE OIG'S USE OF DATA

The OIG's study references CMS's mark-up of 67 percent over the wholesale price, presented in CMS's August, 1999 proposed inherent reasonableness notice for selected products. The OIG reports that CMS developed this 67 percent mark-up by comparing wholesale prices to suggested retail prices, provided in coding applications. However, CMS's methodology for developing that mark-up amount did not account for many costs unique to Medicare, not the least of which is the cost of billing under the Medicare program.

Also, market wholesale prices are significantly different from the wholesale prices paid by the VA. To do business with the VA, its regulations require manufacturers to discount their wholesale prices (if they provide wholesale pricing) or substantially discount their list prices, below any other customer. The 67 percent amount significantly underestimates the difference in costs between providing products to the VA and to other purchasers, including Medicare providers and suppliers.

ACHIEVING APPROPRIATE PAYMENTS—INHERENT REASONABLENESS AUTHORITY

AdvaMed supports the goal of seeking greater economy and efficiency in Medicare payment programs, and believes CMS has the authority necessary to make appropriate payment changes. The Balanced Budget Act (BBA) of 1997 included provisions to streamline the procedures that the CMS and its carriers must follow in using the inherent reasonableness process to adjust Medicare payment levels.

This authority, however, must be used in a predictable and valid way and many concerns have been raised about CMS' implementation of it. The lack of a valid approach to assessing the inherent reasonableness and in proposing new reimbursement rates for certain durable medical equipment (DME) products, led the General Accounting Office (GAO), in 2000, to recommend that CMS: "develop and implement a more structured survey design, including sample selection, survey instrumentation, and data collection methods, and ensure that the design is consistently used by all entities conducting the survey." GAO also recommended that CMS:

—in its final rule implementing the inherent reasonableness process, "define with sufficient clarity the terms grossly excessive, and grossly deficient"
—"collect and analyze additional information to more precisely estimate any payment reductions for glucose test strips, albuterol sulfate, and enteral formulas, as well as for additional payment reductions in subsequent years for lancets, eyeglass frames, latex Foley catheters, and catheter insertion trays without drainage bags"
—monitor indicators that could signal potential problems with patient access to the product groups for which it is reducing maximum payments, and act quickly to rectify any problems that arise.

Under the Balanced Budget Refinement Act (BBRA) of 1999, Congress not only mandated the GAO study, but also prohibited IR implementation until final regulations were published. The House and Senate Conference Agreement specifically stated that IR authority "should be administered judiciously and applied only after public concerns and suggestions about proposed administrative criteria have been openly addressed." Since more than three years have passed, we believe that the best way to accomplish this is through a new notice of proposed rulemaking.

AdvaMed has been working with Congress and the Administration for many years to assure the appropriate implementation of CMS's inherent reasonableness authority. A new notice of proposed rulemaking on the use of inherent reasonableness authority should permit a meaningful exchange of comments on CMS's position, and address the following concerns:

—CMS should base its IR determination on an analysis of the marketplace for the items and services under review using statistically valid market data and sound methodology.
—CMS should use the higher due process procedures specified in existing regulations if payment levels are proposed to be changed by more than 15 percent in any period less than five years.
—CMS should use national-level due process procedures when two or more local carriers acting in concert or any regional carrier make a determination that a reduction is necessary.
—CMS should improve the process for making changes of less than 15 percent in any period less than five years. * CMS should provide an appeals mechanism for review.

The Small Business Administration (SBA) had similar concerns regarding CMS's implementation of the BBA 1997 IR authority, especially its impact on small business. In a 1998 letter to the CMS Administrator, the SBA said: "If Congress intended for HCFA [CMS] to skirt the notice and comment requirements when the reduction exceeds 15 percent, Congress probably would not have bothered to put in any notice and comment requirements in the first place." Further, the SBA asserted that CMS should use notice and comment even in reductions of less than 15 percent, arguing that BBA 1997 is silent on the matter: "Since the language in the BBA did not specify or require that HCFA [CMS] should bypass notice and comment when the fee reduction falls below 15 percent, the office of Advocacy believes that HCFA [CMS] should subject such reductions to notice and comment as a matter of good administrative policy."

AdvaMed seeks to work with Congress and the Administration to ensure that CMS's processes for implementing pricing programs must be open, transparent, collaborative, and responsive.

COMPETITIVE BIDDING CONCERNS

In an effort to address payments for medical supplies, the BBA of 1997 also included a demonstration project to test out the feasibility of using competitive bidding methodologies. In reviewing the short duration of the competitive bidding demonstrations, the IG report quotes an estimated savings from price cuts of 17 percent under the Polk County, Florida competitive bidding demonstration projects. We believe that this amount overstates the actual savings to Medicare, and that there are many procedural problems raised by this demonstration project.

The projects in Florida and Texas have not yet generated a working model that can be replicated for other geographic areas and for other products. It is not known how competitive bidding will impact patient access to the latest life-saving and life-enhancing medical technologies. Nor have the full costs of the effort been determined, including those associated with the significant administrative infrastructure, system changes, and physician, beneficiary and provider education activities that are required in a venture of this sort. These costs are likely to cut deeply into the savings derived from the bidding process. And, according to CBO testimony before the Senate Finance Committee in 1999, "potential savings will erode over time."

The IG study methodology oversimplified and combined price reductions under IR and competitive bidding. AdvaMed believes that it is inappropriate and unnecessary to combine these approaches. With appropriate implementation of IR authority, competitive bidding is unnecessary.

CONCLUSION

AdvaMed looks forward to working with Congress and the Administration on ways to achieve greater economy and efficiency in Medicare payment programs. Unfortunately, the OIG's study does not provide helpful information for achieving this goal. The purchasing and pricing of certain DME products by the Veterans Administration for the provision of services to veterans is not applicable to Medicare in its role as a payer of services. And, the data used by the OIG are inadequate to support the study's broad conclusions.

AdvaMed supports the use of IR authority in a predictable, open and transparent fashion to correct any Medicare overpayments or underpayments. AdvaMed remains concerned about the effectiveness of competitive bidding models in general and believe it is premature to apply competitive bidding nationwide. We recommend that CMS issue a new notice of proposed rulemaking with comment period to fully describe its inherent reasonableness authority, including conducting valid market surveys, and instituting due process procedures.

CONCLUSION OF HEARING

Senator HARKIN. Thank you all very much for being here, that concludes our hearing.

[Whereupon, at 11:32 a.m., Wednesday, June 12, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

○